



Clinical trial results:

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Sirukumab in the Treatment of Patients with Giant Cell Arteritis

Summary

EudraCT number	2015-001758-14
Trial protocol	DE ES NL BG HU BE IT
Global end of trial date	21 March 2018

Results information

Result version number	v1
This version publication date	26 April 2019
First version publication date	26 April 2019

Trial information

Trial identification

Sponsor protocol code	201677
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GSK Response Center, 8664357343 1, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 July 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	21 March 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To investigate the efficacy of sirukumab (100 mg q2w for 12 months) as compared to placebo, each administered in addition to a 6-month prednisone treatment regimen

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 October 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 19
Country: Number of subjects enrolled	Belgium: 14
Country: Number of subjects enrolled	Bulgaria: 4
Country: Number of subjects enrolled	France: 5
Country: Number of subjects enrolled	Germany: 42
Country: Number of subjects enrolled	Hungary: 3
Country: Number of subjects enrolled	Italy: 11
Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	New Zealand: 4
Country: Number of subjects enrolled	Spain: 11
Country: Number of subjects enrolled	United Kingdom: 15
Country: Number of subjects enrolled	United States: 27
Worldwide total number of subjects	161
EEA total number of subjects	111

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	42
From 65 to 84 years	112
85 years and over	7

Subject disposition

Recruitment

Recruitment details:

This was a multicenter, randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of sirukumab in treatment of participants with Giant Cell Arteritis (GCA). A total of 161 participants were enrolled.

Pre-assignment

Screening details:

This study was conducted in 2 distinct parts (Part A and Part B), Part A was a 52-week double-blind treatment phase and Part B was a 104-week long-term extension phase with the option to receive open-label sirukumab (SIR) (up to a 52-week duration of open-label treatment). This study was terminated early by sponsor.

Period 1

Period 1 title	Part A (52 weeks)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Data analyst, Carer, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A:SIR 100 mg SC q2w+6 month prednisone

Arm description:

Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen

Arm type	Experimental
Investigational medicinal product name	Sirukumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

1.0 milliliter Pre-filled syringe by subcutaneous route, every 2 weeks (treatment arms A & B) and subcutaneous, every 4 weeks (treatment arm C)

Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablets, Up to-60 mg/day 20-60 mg/day open-label then 0-18 mg/day taper (blinded)

Arm title	Part A:SIR 100 mg SC q2w+3 month prednisone
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Arm description:

Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen

Arm type	Experimental
Investigational medicinal product name	Sirukumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:	
1.0 milliliter Pre-filled syringe by subcutaneous route, every 2 weeks (treatment arms A & B) and subcutaneous, every 4 weeks (treatment arm C)	
Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Oral tablets, Up to-60 mg/day 20-60 mg/day open-label then 0-18 mg/day taper (blinded)	
Arm title	Part A:SIR 50 mg SC q4w+6 month prednisone
Arm description:	
Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Arm type	Experimental
Investigational medicinal product name	Sirukumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
1.0 milliliter Pre-filled syringe by subcutaneous route, every 2 weeks (treatment arms A & B) and subcutaneous, every 4 weeks (treatment arm C)	
Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Oral tablets, Up to-60 mg/day 20-60 mg/day open-label then 0-18 mg/day taper (blinded)	
Arm title	Part A:Placebo SC q2w + 6 month prednisone
Arm description:	
Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Arm type	Placebo
Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Oral tablets, Up to-60 mg/day 20-60 mg/day open-label then 0-18 mg/day taper (blinded)	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
subcutaneous every 2 weeks (treatment arms D & E)	
Arm title	Part A:Placebo SC q2w+12 month prednisone
Arm description:	
Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month	

prednisone taper regimen

Arm type	Placebo
Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablets, Up to-60 mg/day 20-60 mg/day open-label then 0-18 mg/day taper (blinded)

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

subcutaneous every 2 weeks (treatment arms D & E)

Number of subjects in period 1	Part A:SIR 100 mg SC q2w+6 month prednisone	Part A:SIR 100 mg SC q2w+3 month prednisone	Part A:SIR 50 mg SC q4w+6 month prednisone
Started	42	39	26
Completed Part A and didn't enter Part B	1 ^[1]	0 ^[2]	1 ^[3]
Completed	8	5	4
Not completed	34	34	22
Physician decision	1	4	3
Consent withdrawn by subject	6	6	1
Sponsor request	24	24	18
Unknown	2	-	-
Lost to follow-up	-	-	-
Protocol deviation	1	-	-

Number of subjects in period 1	Part A:Placebo SC q2w + 6 month prednisone	Part A:Placebo SC q2w+12 month prednisone
Started	27	27
Completed Part A and didn't enter Part B	0 ^[4]	0 ^[5]
Completed	5	4
Not completed	22	23
Physician decision	1	-
Consent withdrawn by subject	3	3
Sponsor request	18	19
Unknown	-	-
Lost to follow-up	-	1
Protocol deviation	-	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 2 Participants completed Part A then withdrew. They are counted again in withdrawals

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 2 Participants completed Part A then withdrew. They are counted again in withdrawals

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 2 Participants completed Part A then withdrew. They are counted again in withdrawals

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 2 Participants completed Part A then withdrew. They are counted again in withdrawals

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 2 Participants completed Part A then withdrew. They are counted again in withdrawals

Period 2

Period 2 title	Part B (104 weeks)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part B: SIR 100 mg SC q2w+6 month prednisone

Arm description:

Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen in Part A

Arm type	Experimental
Investigational medicinal product name	Sirukumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

1.0 milliliter Pre-filled syringe by subcutaneous route, every 2 weeks (treatment arms A & B) and subcutaneous, every 4 weeks (treatment arm C)

Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablets, Up to-60 mg/day 20-60 mg/day open-label then 0-18 mg/day taper (blinded)

Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablets, Up to-60 mg/day 20-60 mg/day open-label then 0-18 mg/day taper (blinded)

Arm title	Part B:SIR 100 mg SC q2w+3 month prednisone
Arm description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen in Part A	
Arm type	Experimental
Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Oral tablets, Up to-60 mg/day 20-60 mg/day open-label then 0-18 mg/day taper (blinded)	
Investigational medicinal product name	Sirukumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 1.0 milliliter Pre-filled syringe by subcutaneous route, every 2 weeks (treatment arms A & B) and subcutaneous, every 4 weeks (treatment arm C)	
Arm title	Part B:SIR 50 mg SC q4w+6 month prednisone
Arm description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen in Part A	
Arm type	Experimental
Investigational medicinal product name	Sirukumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 1.0 milliliter Pre-filled syringe by subcutaneous route, every 2 weeks (treatment arms A & B) and subcutaneous, every 4 weeks (treatment arm C)	
Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Oral tablets, Up to-60 mg/day 20-60 mg/day open-label then 0-18 mg/day taper (blinded)	
Arm title	Part B:Placebo SC q2w + 6 month prednisone
Arm description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen in Part A	
Arm type	Experimental
Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Oral tablets, Up to-60 mg/day 20-60 mg/day open-label then 0-18 mg/day taper (blinded)	

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: subcutaneous every 2 weeks (treatment arms D & E)	
Arm title	Part B:Placebo SC q2w + 12 month prednisone

Arm description:

Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen in Part A

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

subcutaneous every 2 weeks (treatment arms D & E)

Number of subjects in period 2	Part B:SIR 100 mg SC q2w+6 month prednisone	Part B:SIR 100 mg SC q2w+3 month prednisone	Part B:SIR 50 mg SC q4w+6 month prednisone
Started	8	5	4
Completed	0	0	0
Not completed	8	5	4
Sponsor request	8	5	3
Lost to follow-up	-	-	1

Number of subjects in period 2	Part B:Placebo SC q2w + 6 month prednisone	Part B:Placebo SC q2w + 12 month prednisone
Started	5	4
Completed	0	0
Not completed	5	4
Sponsor request	5	4
Lost to follow-up	-	-

Baseline characteristics

Reporting groups

Reporting group title	Part A (52 weeks)
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Reporting group description: -

Reporting group values	Part A (52 weeks)	Total	
Number of subjects	161	161	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	42	42	
From 65-84 years	112	112	
85 years and over	7	7	
Age Continuous			
Units: Years			
arithmetic mean	69.6		
standard deviation	± 7.85	-	
Sex: Female, Male			
Units: Subjects			
Female	124	124	
Male	37	37	
Race, Customized			
Units: Subjects			
African American/African Heritage	1	1	
White: Arabic/North African Heritage	2	2	
White/Caucasian/European Heritage	156	156	
Mixed Race	2	2	

End points

End points reporting groups

Reporting group title	Part A:SIR 100 mg SC q2w+6 month prednisone
Reporting group description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Reporting group title	Part A:SIR 100 mg SC q2w+3 month prednisone
Reporting group description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Reporting group title	Part A:SIR 50 mg SC q4w+6 month prednisone
Reporting group description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Reporting group title	Part A:Placebo SC q2w + 6 month prednisone
Reporting group description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Reporting group title	Part A:Placebo SC q2w+12 month prednisone
Reporting group description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Reporting group title	Part B:SIR 100 mg SC q2w+6 month prednisone
Reporting group description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen in Part A	
Reporting group title	Part B:SIR 100 mg SC q2w+3 month prednisone
Reporting group description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen in Part A	
Reporting group title	Part B:SIR 50 mg SC q4w+6 month prednisone
Reporting group description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen in Part A	
Reporting group title	Part B:Placebo SC q2w + 6 month prednisone
Reporting group description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen in Part A	
Reporting group title	Part B:Placebo SC q2w + 12 month prednisone
Reporting group description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen in Part A	
Subject analysis set title	SIR100 mg SC q2w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	SIR 100 mg SC q2w+3 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	SIR 50 mg SC q4w+6 month prednisone

Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	Placebo SC q2w + 6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	Placebo SC q2w + 12 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Subject analysis set title	PartA:SIR 100 mg SC q2w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartA:SIR 100 mg SC q2w+3 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartA:SIR 50 mg SC q4w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartA:Placebo SC q2w + 6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartA:Placebo SC q2w + 12 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartA:SIR 100 mg SC q2w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartA:SIR 100 mg SC q2w+3 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartA:SIR 50 mg SC q4w+6 month prednisone

Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartA:Placebo SC q2w + 6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartA:Placebo SC q2w + 12 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+3 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 12 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Subject analysis set title	PartA:SIR 100 mg SC q2w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartA:SIR 100 mg SC q2w+6 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartA:SIR 100 mg SC q2w+3 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartA:SIR 50 mg SC q4w+6 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartA:Placebo SC q2w + 6 month Prednisone

Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartA:Placebo SC q2w + 12 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Subject analysis set title	PartA:SIR 100 mg SC q2w+6 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartA:SIR 100 mg SC q2w+3 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartA:SIR 50 mg SC q4w+6 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartA:Placebo SC q2w + 6 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartA:Placebo SC q2w + 12 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+6 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+3 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 6 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 12 month Prednisone

Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+6 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+3 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 6 month Prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+3 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 12 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+3 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 6 month prednisone

Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartBSIR 100 mg SC q2w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartBSIR 100 mg SC q2w+3 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartBSIR 50 mg SC q4w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartBPlacebo SC q2w + 6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartBPlacebo SC q2w + 12 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+3 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 12 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+3 month prednisone

Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 12 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen	
Subject analysis set title	PartB:SIR 100 mg SC q2w+6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen	
Subject analysis set title	PartB:Placebo SC q2w + 6 month prednisone
Subject analysis set type	Full analysis
Subject analysis set description: Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen	

Primary: Part A: Number of participants in sustained remission at Week 52

End point title	Part A: Number of participants in sustained remission at Week 52 ^[1]
End point description: Sustained remission was defined as having achieved all of the following: 1) remission at Week 12, 2) absence of disease flare Week 12 through Week 52, 3) completion of the assigned prednisone taper, and 4) no requirement for rescue therapy through Week 52. Remission was defined as absence of clinical signs and symptoms of GCA and normalization of erythrocyte sedimentation rate (ESR) [<30 millimeters per hour] and C-reactive Protein (CRP) [<1 milligram/deciliter]) and flare was defined as recurrence of symptoms attributable to active GCA, with or without elevations in ESR and/or CRP. Data for number of participants in sustained remission at Week 52 is presented. Only those participants who completed Week 52 visit or withdrew before 10 Oct 2017 were included in the analysis.	
End point type	Primary
End point timeframe: Week 52	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was performed

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	13	9	9
Units: Participants	3	2	1	0

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of participants who remained in sustained remission without requirement for rescue therapy or treatment change at Week 24

End point title	Part B: Number of participants who remained in sustained remission without requirement for rescue therapy or treatment change at Week 24
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End point description:

Participants who remained in sustained remission without requirement for rescue therapy or treatment change at each scheduled visit of Part B were defined as participants having achieved all of the following criteria: 1. Participants in sustained remission at the Week 52 visit of Part A, 2. Absence of disease flare, 3. No requirement for rescue therapy at any time through Week 24 of Part B, 4. No requirement for treatment change at any time through Week 24 of Part B. Remission was defined as absence of clinical signs and symptoms of GCA and normalization of ESR [<30 millimeters per hour] and CRP [<1 milligram/deciliter]) and flare was defined as recurrence of symptoms attributable to active GCA, with or without elevations in ESR and/or CRP.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Part B:SIR 100 mg SC q2w+6 month prednisone	Part B:SIR 100 mg SC q2w+3 month prednisone	Part B:SIR 50 mg SC q4w+6 month prednisone	Part B:Placebo SC q2w + 6 month prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	1	0 ^[2]
Units: Participants	99999	99999	99999	

Notes:

[2] - Data for number of participants in sustained remission over time for Part B is presented.

End point values	Part B:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	0 ^[3]	2		
Units: Participants		99999		

Notes:

[3] - Data for number of participants in sustained remission over time for Part B is presented.

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Cumulative prednisone dose over time

End point title	Part A: Cumulative prednisone dose over time
End point description:	
Cumulative prednisone is the dose from the taper (both open-label and blinded) as well as from the corticosteroid rescue therapies. Cumulative dose at the specified Week was derived as the sum of all the doses from Baseline to the specified Week at each visit was calculated based on the number of participants who attended that visit. For the main analysis of cumulative prednisone dose over time. Data for Prednisone Dose- Study Drug and Prednisone Equivalent Concomitant Therapy for part A is presented. ITT population and the number of participants included at specific time points were based on the participants who attended a scheduled or unscheduled visit mapped to that time point and received a total prednisone dose greater than 0 mg.	
End point type	Secondary
End point timeframe:	
Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52	

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Milligrams				
arithmetic mean (standard deviation)				
Week 2, n= 40,39,26,27,26	439.575 (± 237.8990)	464.923 (± 299.6445)	424.577 (± 270.2183)	432.815 (± 315.6851)
Week 4,n=40,39,26,25,27	701.100 (± 370.9798)	741.115 (± 436.4205)	701.192 (± 439.7251)	705.480 (± 601.9706)
Week 8,n=37, 37,26,23,26	1086.676 (± 600.7400)	987.730 (± 559.4458)	1014.731 (± 592.3515)	1161.391 (± 1202.8504)
Week 12,n=34,32,24,22,24	1344.441 (± 779.6775)	1063.773 (± 619.4002)	1208.167 (± 650.6975)	1379.409 (± 1255.4397)
Week 16,n=32,30,24,22,22	1545.602 (± 964.3264)	1182.288 (± 718.6186)	1348.750 (± 689.2484)	1672.795 (± 1261.7121)
Week 20,n=29,27,21,24,19	1690.302 (± 1173.6005)	1339.546 (± 888.5007)	1475.786 (± 734.7667)	1646.177 (± 701.5240)
Week 24,n=30,25,19,18,17	1878.458 (± 1333.1175)	1495.015 (± 1055.9615)	1626.342 (± 813.8284)	1917.444 (± 861.6887)
Week 28,n=24,23,15,17,15	2000.813 (± 1594.5982)	1575.549 (± 1170.7294)	1797.533 (± 933.3753)	2141.294 (± 1082.2754)
Week 32,n=19,21,13,15,18	2216.000 (± 1953.8211)	1716.863 (± 1328.1426)	1859.346 (± 858.5431)	2531.417 (± 1327.9125)
Week 36,n=19,17,14,13,14	2321.711 (± 2090.2393)	1803.919 (± 1536.5304)	1705.214 (± 802.8858)	2617.817 (± 1636.2516)
Week 40,n=18,15,11,13,12	2003.264 (± 1426.0271)	2023.342 (± 1651.4092)	1842.500 (± 904.4136)	2960.144 (± 1736.2249)
Week 44,n=17,13,10,12,13	2051.603 (± 1588.9627)	1481.115 (± 1381.3957)	1980.733 (± 1444.8664)	2783.542 (± 1776.0608)
Week 48,n=10,16,9,8,11	1821.325 (± 1139.5986)	1601.656 (± 1362.9717)	1562.333 (± 828.5650)	2859.208 (± 1882.7422)
Week 52,n=11,10,6,7,6	2974.295 (± 2966.6259)	2418.213 (± 2085.2345)	2556.222 (± 1363.1832)	3157.054 (± 1988.0610)

End point values	PartA:Placebo SC q2w + 12			
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	month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Milligrams				
arithmetic mean (standard deviation)				
Week 2, n= 40,39,26,27,26	430.846 (± 241.3540)			
Week 4,n=40,39,26,25,27	751.407 (± 431.3442)			
Week 8,n=37, 37,26,23,26	1129.077 (± 546.8037)			
Week 12,n=34,32,24,22,24	1462.917 (± 630.1717)			
Week 16,n=32,30,24,22,22	1729.977 (± 701.3734)			
Week 20,n=29,27,21,24,19	2041.632 (± 771.3504)			
Week 24,n=30,25,19,18,17	2299.471 (± 840.8758)			
Week 28,n=24,23,15,17,15	2387.800 (± 741.1663)			
Week 32,n=19,21,13,15,18	2404.500 (± 808.8642)			
Week 36,n=19,17,14,13,14	2717.696 (± 897.0689)			
Week 40,n=18,15,11,13,12	2963.865 (± 909.0195)			
Week 44,n=17,13,10,12,13	2954.760 (± 1022.5491)			
Week 48,n=10,16,9,8,11	3167.898 (± 1195.4020)			
Week 52,n=11,10,6,7,6	3603.229 (± 1477.6777)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of participants in sustained remission over time

End point title	Part B: Number of participants in sustained remission over time
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End point description:

Sustained remission was defined as having achieved all of the following: 1) remission at Week 12 (absence of signs and symptoms of GCA and normalization of ESR and CRP), 2) absence of disease flare Week 12 through Week 52 with or without elevations in ESR and/or CRP, 3) completion of the assigned prednisone taper, and 4) no requirement for rescue therapy through Week 52. Remission was defined as absence of clinical signs and symptoms of GCA and normalization of ESR [<30 millimeters per hour] and CRP [<1 milligram/deciliter]) and Flare was defined as recurrence of symptoms attributable to active GCA, with or without elevations in ESR and/or CRP. Data for number of participants in sustained remission over time for Part B is presented. ITT-Part B Population. Only participants who were in sustained remission at Week 52 of Part A, who Completed the Week X Visit of Part B or who Withdraw before 10th of October 2017 were included in the analysis.

End point type	Secondary
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End point timeframe:

Weeks 4, 8 and 12

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	2	1	99999 ^[4]
Units: Participants				
Week 4,n=1,1,1,0,0	1	1	1	99999
Week 8,n=1,0,1,0,0	1	99999	1	99999
Week 12,n=1,0,0,0,0	1	99999	99999	99999

Notes:

[4] - Data for number of participants in sustained remission over time for Part B is presented.

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	99999 ^[5]			
Units: Participants				
Week 4,n=1,1,1,0,0	99999			
Week 8,n=1,0,1,0,0	99999			
Week 12,n=1,0,0,0,0	99999			

Notes:

[5] - Data for number of participants in sustained remission over time for Part B is presented.

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Time to first disease flare after clinical remission

End point title	Part A: Time to first disease flare after clinical remission
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End point description:

Clinical remission was defined as absence of clinical signs and symptoms of GCA, which was determined by a lack of flare for the participant. If a participant had a flare, they had one or more signs and symptoms, and therefore are not considered as being in clinical remission. Time to first disease flare (days) was calculated as (Date of First Flare - Date of Clinical Remission + 1 day). Data for Time to first disease flare after clinical remission for part A is presented.

End point type	Secondary
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End point timeframe:

Week 52

End point values	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone	PartA:Placebo SC q2w + 12 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	39	26	27	27
Units: Days				
median (inter-quartile range (Q1-Q3))	99999 (-99999 to 99999)	99999 (176.0 to 99999)	99999 (99.0 to 99999)	99999 (183.0 to 99999)

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	40			
Units: Days				
median (inter-quartile range (Q1-Q3))	99999 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Time to first disease flare for participants in sustained remission

End point title	Part B: Time to first disease flare for participants in sustained remission
End point description:	
Clinical remission was defined as absence of clinical signs and symptoms of GCA. If a participant had a flare, they had one or more signs and symptoms, and therefore are not considered as being in clinical remission. Time to event (days) is defined as the duration in days from the date of the Week 52 visit of Part A to the start date of Event (Date of First Flare - Date of Week 52 visit of Part A + 1). Data for Time to first disease flare after clinical remission for part B is presented.	
End point type	Secondary
End point timeframe:	
Week 52	

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	2	1	0 ^[6]
Units: Days				
median (inter-quartile range (Q1-Q3))	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	(to)

Notes:

[6] - Data for number of participants in sustained remission over time for Part B is presented.

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	0 ^[7]			
Units: Days				
median (inter-quartile range (Q1-Q3))	(to)			

Notes:

[7] - Data for number of participants in sustained remission over time for Part B is presented.

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of disease flares over time

End point title	Part A: Number of disease flares over time
End point description:	
This summarizes disease flares over time with no adjustment for exposure to study drugs, calculated by taking the last visit before a participant withdrew and then counting the number of participants with at least 1 flare up to that point and summing up the total number of flares experienced by each of these participants; participants who did not reach Week 2 were not included in this analysis. Data for number of disease flares per participant over time for part A were presented.	
End point type	Secondary
End point timeframe:	
Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52	

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Disease flares				
Week 2, n=38, 39,26,25,27	1	2	2	0
Week 4, n=37,37,25,23,27	3	4	3	0
Week 8, n=34,32,24,23,23	2	6	3	1
Week 12, n=32,29,24,22,22	4	9	4	4
Week 16, n=28,26,22,19,19	4	9	5	9
Week 20, n=26,23,19,18,16	4	9	6	10
Week 24, n=23,21,16,17,16	6	9	8	11
Week 28, n=19,18,12,14,14	5	8	8	11
Week 32, n=19,15,10,12,13	5	8	5	10
Week 36, n=15,13,10,12,13	3	8	5	10
Week 40, n=15,11,9,10,10	2	7	5	8
Week 44, n=11,11,6,8,9	1	8	3	6
Week 48, n=9,8,5,8,5	1	4	1	7
Week 52, n=9,5,5,5,4	1	2	1	7

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Disease flares				
Week 2, n=38, 39,26,25,27	2			
Week 4, n=37,37,25,23,27	2			
Week 8, n=34,32,24,23,23	5			
Week 12, n=32,29,24,22,22	4			
Week 16, n=28,26,22,19,19	4			
Week 20, n=26,23,19,18,16	3			
Week 24, n=23,21,16,17,16	5			
Week 28, n=19,18,12,14,14	5			
Week 32, n=19,15,10,12,13	6			
Week 36, n=15,13,10,12,13	6			
Week 40, n=15,11,9,10,10	5			
Week 44, n=11,11,6,8,9	7			
Week 48, n=9,8,5,8,5	3			
Week 52, n=9,5,5,5,4	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of participants with at least one hospitalization for disease flare

End point title	Part A: Number of participants with at least one hospitalization for disease flare
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End point description:

Number of participants with at least one hospitalization for disease flare at a given visit is the number of participants with at least one hospitalization for disease flare between first SC IP intake and the day of the given visit. Data for participants requiring at least one hospitalization for disease flare for part A is presented.

End point type	Secondary
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End point timeframe:

Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Participants				
Week 2, n=38, 39,26,25,27	0	0	0	0
Week 4, n=37,37,25,23,27	0	0	0	0
Week 8, n=34,32,24,23,23	0	0	0	0
Week 12, n=32,29,24,22,22	1	0	0	0
Week 16, n=28,26,22,19,19	1	0	0	0
Week 20, n=26,23,19,18,16	1	0	1	0
Week 24, n=23,21,16,17,16	1	0	1	0
Week 28, n=19,18,12,14,14	0	0	1	0
Week 32, n=19,15,10,12,13	0	0	0	0
Week 36, n=15,13,10,12,13	0	0	0	0
Week 40, n=15,11,9,10,10	0	0	0	0
Week 44, n=11,11,6,8,9	0	0	0	0
Week 48, n=9,8,5,8,5	0	0	0	0
Week 52, n=9,5,5,5,4	0	0	0	0

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Participants				
Week 2, n=38, 39,26,25,27	0			
Week 4, n=37,37,25,23,27	0			
Week 8, n=34,32,24,23,23	0			
Week 12, n=32,29,24,22,22	0			
Week 16, n=28,26,22,19,19	0			
Week 20, n=26,23,19,18,16	0			
Week 24, n=23,21,16,17,16	0			
Week 28, n=19,18,12,14,14	0			
Week 32, n=19,15,10,12,13	0			
Week 36, n=15,13,10,12,13	0			
Week 40, n=15,11,9,10,10	0			
Week 44, n=11,11,6,8,9	0			
Week 48, n=9,8,5,8,5	0			
Week 52, n=9,5,5,5,4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of hospitalizations for disease flare over time

End point title	Part A: Number of hospitalizations for disease flare over time
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End point description:

Number of hospitalizations for disease flare at given visit is the number of hospitalizations for disease flare between first SC IP intake and the day of the of the given visit.. Data for number of hospitalizations for disease flare over time for part A was presented.

End point type	Secondary
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End point timeframe:

Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Number of Hospitalizations				
Week 2, n=38, 39,26,25,27	0	0	0	0
Week 4, n=37,37,25,23,27	0	0	0	0
Week 8, n=34,32,24,23,23	0	0	0	0
Week 12, n=32,29,24,22,22	2	0	0	0
Week 16, n=28,26,22,19,19	2	0	0	0
Week 20, n=26,23,19,18,16	2	0	1	0
Week 24, n=23,21,16,17,16	2	0	1	0
Week 28, n=19,18,12,14,14	0	0	1	0
Week 32, n=19,15,10,12,13	0	0	0	0
Week 36, n=15,13,10,12,13	0	0	0	0
Week 40, n=15,11,9,10,10	0	0	0	0
Week 44, n=11,11,6,8,9	0	0	0	0
Week 48, n=9,8,5,8,5	0	0	0	0
Week 52, n=9,5,5,5,4	0	0	0	0

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Number of Hospitalizations				
Week 2, n=38, 39,26,25,27	0			
Week 4, n=37,37,25,23,27	0			
Week 8, n=34,32,24,23,23	0			
Week 12, n=32,29,24,22,22	0			
Week 16, n=28,26,22,19,19	0			
Week 20, n=26,23,19,18,16	0			
Week 24, n=23,21,16,17,16	0			
Week 28, n=19,18,12,14,14	0			
Week 32, n=19,15,10,12,13	0			

Week 36, n=15,13,10,12,13	0			
Week 40, n=15,11,9,10,10	0			
Week 44, n=11,11,6,8,9	0			
Week 48, n=9,8,5,8,5	0			
Week 52, n=9,5,5,5,4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Mean 36-item Short Form health survey version 2 (SF-36 v2) acute score over time

End point title	Part A: Mean 36-item Short Form health survey version 2 (SF-36 v2) acute score over time
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End point description:

SF-36v2 acute health survey questionnaire consists of the following 8 multi-item scales: 1. Limitations in physical functioning due to health problems, 2. Limitations in usual role activities due to physical health problems, 3. Bodily pain, 4. General mental health (psychological distress and well-being), 5. Limitations in usual role activities due to personal or emotional problems, 6. Limitations in social functioning due to physical or mental health problems. 7. Vitality (energy and fatigue) and 8. General health perception. These 8 scales were scored from 0 to 100, 0 (worst score) to 100 (best score) where higher scores indicates better health. Data for Physical Component Summary (PCS), Mental Component Summary (MCS) scores was presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0), Weeks 12, 24, 36, 52

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Scores on scale				
arithmetic mean (standard deviation)				
PCS,Baseline, n=42,38,25,23,27	49.258 (± 11.7655)	43.271 (± 12.3169)	42.919 (± 11.7298)	49.240 (± 9.2759)
PCS,Week 12, n=31,28,24,22,22	51.519 (± 10.5352)	43.128 (± 11.4559)	43.655 (± 11.0324)	48.552 (± 10.4184)
PCS,Week 24, n=23,20,15,17,16	50.023 (± 11.4731)	45.677 (± 12.1192)	45.097 (± 15.0552)	46.911 (± 9.2901)
PCS,Week 36, n=15,13,10,12,13	51.989 (± 10.7521)	47.069 (± 12.7103)	46.005 (± 12.2496)	48.336 (± 10.0154)
PCS,Week 52, n=9,5,5,5,4	50.269 (± 10.8743)	53.690 (± 7.9049)	53.608 (± 7.7721)	52.026 (± 6.4892)
MCS,Week 12, n=31,28,24,22,22	43.955 (± 4.6164)	45.264 (± 5.7982)	46.393 (± 6.1792)	43.746 (± 5.3179)
MCS,Week 24, n=23,20,15,17,16	44.538 (± 5.6952)	45.954 (± 5.4884)	44.877 (± 6.5210)	45.372 (± 6.4561)
MCS,Week 36, n=15,13,10,12,13	45.258 (± 5.2429)	45.540 (± 4.8330)	44.550 (± 6.7199)	42.959 (± 4.8484)
MCS,Week 52, n=9,5,5,5,4	44.810 (± 6.4757)	45.008 (± 2.2373)	42.004 (± 5.5695)	42.258 (± 4.1002)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Scores on scale				
arithmetic mean (standard deviation)				
PCS,Baseline, n=42,38,25,23,27	45.470 (\pm 12.8498)			
PCS,Week 12, n=31,28,24,22,22	47.007 (\pm 12.8749)			
PCS,Week 24, n=23,20,15,17,16	44.280 (\pm 11.4740)			
PCS,Week 36, n=15,13,10,12,13	44.946 (\pm 10.1921)			
PCS,Week 52, n=9,5,5,5,4	53.143 (\pm 12.8351)			
MCS,Week 12, n=31,28,24,22,22	43.182 (\pm 4.6707)			
MCS,Week 24, n=23,20,15,17,16	45.526 (\pm 5.8924)			
MCS,Week 36, n=15,13,10,12,13	46.755 (\pm 4.8284)			
MCS,Week 52, n=9,5,5,5,4	42.125 (\pm 1.9020)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Mean EuroQol – 5 dimensions, 5 levels (EQ-5D-5L) Index score over time

End point title	Part A: Mean EuroQol – 5 dimensions, 5 levels (EQ-5D-5L) Index score over time
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End point description:

EQ-5D essentially consists of 2 elements: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The EQ-5D descriptive system comprised of the following 5 dimensions: 1.Mobility, 2.Self-Care, 3.Usual Activities, 4.Pain/Discomfort and 5.Anxiety/Depression. Each of these 5 dimensions has 5 levels: 1: no problems; 2: slight problems; 3: moderate problems; 4: severe problems; 5: Unable to do. The digits for each of the 5 dimensions were combined in a 5-digit number describing the participant's health state: e.g. state 11111 indicates no problem on any of the 5 dimensions. The index score was derived from the 5 dimensions scores using UK tariff. The weights based from the UK population was used for the conversion, regardless of the origin country of participant. The score ranged from -0.594 (worst score) to 1 (best score).

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 12, 24, 36, 52

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,38,25,23,27	0.7918 (± 0.20589)	0.6681 (± 0.31299)	0.6912 (± 0.19348)	0.7429 (± 0.22387)
Week 12, n=31,28,24,22,22	0.7866 (± 0.22042)	0.7024 (± 0.22087)	0.7452 (± 0.17942)	0.7228 (± 0.16993)
Week 24, n=23,20,15,17,16	0.7485 (± 0.20310)	0.7217 (± 0.21397)	0.7135 (± 0.24006)	0.7323 (± 0.10346)
Week 36, n=15,13,10,12,13	0.8011 (± 0.13468)	0.7454 (± 0.22373)	0.7774 (± 0.11809)	0.6950 (± 0.15242)
Week 52, n=9,5,5,5,4	0.8210 (± 0.13502)	0.7628 (± 0.15352)	0.8092 (± 0.04275)	0.7864 (± 0.05892)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,38,25,23,27	0.7554 (± 0.16610)			
Week 12, n=31,28,24,22,22	0.7069 (± 0.22289)			
Week 24, n=23,20,15,17,16	0.7301 (± 0.11498)			
Week 36, n=15,13,10,12,13	0.7506 (± 0.17536)			
Week 52, n=9,5,5,5,4	0.8068 (± 0.06050)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Mean EQ-5D-5L Visual Analogue Scale (VAS) over time

End point title	Part A: Mean EQ-5D-5L Visual Analogue Scale (VAS) over time
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End point description:

EQ-5D essentially consists of 2 elements: the EQ-5D descriptive system and the EQ VAS. The EQ-5D descriptive system comprised of the following 5 dimensions: 1.Mobility, 2.Self-Care, 3.Usual Activities, 4.Pain/Discomfort and 5.Anxiety/Depression. Each of these 5 dimensions has 5 levels: 1: no problems; 2: slight problems; 3: moderate problems; 4: severe problems; 5: Unable to do. The digits for each of the 5 dimensions were combined in a 5-digit number describing the participant's health state: e.g. state 11111 indicates no problem on any of the 5 dimensions. The index score was derived from the 5 dimensions scores using UK tariff. The weights based from the UK population was used for the conversion, regardless of the origin country of participant. The score ranged from -0.594 (worst score) to 1 (best score). The EQ VAS records the respondent's self-rated health on a vertical line, VAS where

the endpoints are 'Best imaginable health state' and 'Worst imaginable health state'.

End point type	Secondary
End point timeframe:	
Baseline (Week 0) and Weeks 12, 24, 36, 52	

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,38,25,23,27	67.0 (± 17.83)	65.6 (± 21.43)	57.0 (± 17.61)	62.1 (± 23.81)
Week 12, n=31,28,24,22,22	74.3 (± 19.77)	64.2 (± 22.89)	68.4 (± 19.39)	63.3 (± 22.61)
Week 24, n=23,20,15,17,16	74.6 (± 16.26)	70.6 (± 24.05)	65.1 (± 23.11)	64.9 (± 19.03)
Week 36, n=15,13,10,12,13	79.5 (± 9.55)	73.9 (± 24.55)	66.9 (± 20.72)	68.3 (± 18.66)
Week 52, n=9,5,5,5,4	79.9 (± 9.74)	80.6 (± 16.50)	78.4 (± 14.77)	60.2 (± 26.33)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,38,25,23,27	65.1 (± 16.00)			
Week 12, n=31,28,24,22,22	65.5 (± 21.33)			
Week 24, n=23,20,15,17,16	61.5 (± 19.71)			
Week 36, n=15,13,10,12,13	61.6 (± 21.29)			
Week 52, n=9,5,5,5,4	70.0 (± 27.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Mean Functional Assessment of Chronic Illness Therapy-fatigue (FACIT-Fatigue) scores over time

End point title	Part A: Mean Functional Assessment of Chronic Illness Therapy-fatigue (FACIT-Fatigue) scores over time
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End point description:

The FACIT-Fatigue is a 13-item questionnaire formatted for self-administration that assesses participant reported fatigue and its impact upon daily activities and function over the past seven days. Participants were asked to answer each question using a 5-point Likert-type scale (4 = Not at all; 3 = A little bit; 2 = Somewhat; 1 = Quite a bit; and 0 = Very Much) where 0 is a bad response and 4 is good response. Each of the 13 items of the FACIT-Fatigue Scale ranges from 0-4, with a range of possible total score

from 0-52, 0 (Extreme fatigue) to 52 (No fatigue) where 0 being the worst possible score and 52 the best (i.e. less fatigue). Scores below 30 indicate severe fatigue. Each negatively-worded item response was recoded so that 0 is a bad response and 4 is good response. All responses were added with equal weight to obtain the total score. The total score was calculated as the sum of all the individual items after recoding some of the items.

End point type	Secondary
End point timeframe:	
Baseline (Week 0), Weeks 12, 24, 36, 52	

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,38,25,23,27	38.7 (± 10.72)	34.2 (± 12.25)	31.1 (± 9.89)	38.0 (± 8.37)
Week 12, n=31,28,24,22,22	40.2 (± 8.83)	32.7 (± 11.25)	34.3 (± 11.12)	38.5 (± 9.82)
Week 24, n=23,20,15,17,16	38.1 (± 10.48)	36.5 (± 13.22)	31.2 (± 13.09)	36.2 (± 6.15)
Week 36, n=15,13,10,12,13	41.4 (± 9.41)	38.4 (± 9.95)	36.9 (± 10.88)	40.9 (± 6.49)
Week 52, n=9,5,5,5,4	42.1 (± 6.72)	43.0 (± 6.48)	40.4 (± 5.22)	44.0 (± 5.48)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,38,25,23,27	34.1 (± 13.32)			
Week 12, n=31,28,24,22,22	35.5 (± 13.34)			
Week 24, n=23,20,15,17,16	36.0 (± 9.18)			
Week 36, n=15,13,10,12,13	37.5 (± 10.02)			
Week 52, n=9,5,5,5,4	41.0 (± 12.25)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Mean Pain Numeric Rating Scale (NRS) scores over time

End point title	Part A: Mean Pain Numeric Rating Scale (NRS) scores over time
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End point description:

The assessment of pain severity was made using a single pain severity item on which participants were asked to rate the severity of their average pain on a 11-point numeric rating scale ranging from 0, "no pain" to 10, "the worst pain imaginable". Data for NRS scores over time for part A is reported.

End point type	Secondary
End point timeframe:	
Baseline (Week 0), Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52	

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,38,25,23,27	1.8 (± 2.31)	2.5 (± 2.97)	3.1 (± 2.27)	2.6 (± 2.09)
Week 2, n=38,38,25,21,27	1.3 (± 1.55)	2.8 (± 3.08)	2.8 (± 1.96)	2.6 (± 2.13)
Week 4, n=36,37,24,22,27	1.7 (± 2.16)	3.1 (± 3.13)	3.3 (± 2.20)	2.4 (± 2.28)
Week 8, n=34,30,24,21,23	1.8 (± 2.42)	2.9 (± 2.73)	3.0 (± 2.54)	2.1 (± 1.96)
Week 12, n=31,28,24,22,22	1.7 (± 2.30)	3.6 (± 3.05)	3.3 (± 2.42)	2.3 (± 2.50)
Week 16, n=27,25,22,19,19	1.4 (± 2.22)	3.3 (± 2.84)	3.0 (± 2.60)	2.4 (± 2.06)
Week 20, n=26,23,19,18,15	1.7 (± 2.27)	2.9 (± 2.70)	3.6 (± 2.63)	1.4 (± 1.54)
Week 24, n=23,20,15,17,16	2.4 (± 2.82)	2.5 (± 2.42)	3.3 (± 2.94)	2.4 (± 1.84)
Week 28, n=18,17,11,13,14	2.6 (± 2.38)	2.8 (± 3.03)	3.6 (± 2.87)	2.3 (± 2.14)
Week 32, n=19,14,9,12,12	2.1 (± 2.57)	1.9 (± 2.67)	2.9 (± 1.90)	2.6 (± 2.15)
Week 36, n=15,13,10,12,13	1.6 (± 1.88)	2.0 (± 2.55)	2.9 (± 2.02)	2.3 (± 2.42)
Week 40, n=15,11,9,10,10	2.0 (± 2.54)	2.0 (± 2.57)	3.1 (± 2.09)	1.9 (± 1.91)
Week 44, n=11,11,6,8,8	2.1 (± 2.74)	1.9 (± 2.47)	2.2 (± 1.72)	1.3 (± 0.71)
Week 48, n=9,8,5,7,5	1.9 (± 2.42)	0.8 (± 1.04)	2.6 (± 0.89)	1.6 (± 1.27)
Week 52, n=9,5,5,5,4	1.3 (± 1.66)	0.8 (± 0.84)	2.8 (± 2.28)	2.2 (± 0.84)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,38,25,23,27	2.6 (± 2.39)			
Week 2, n=38,38,25,21,27	2.6 (± 2.63)			
Week 4, n=36,37,24,22,27	1.8 (± 1.72)			
Week 8, n=34,30,24,21,23	3.3 (± 2.82)			
Week 12, n=31,28,24,22,22	2.0 (± 2.08)			
Week 16, n=27,25,22,19,19	2.7 (± 2.16)			
Week 20, n=26,23,19,18,15	2.7 (± 2.02)			
Week 24, n=23,20,15,17,16	3.5 (± 2.22)			
Week 28, n=18,17,11,13,14	2.9 (± 2.40)			
Week 32, n=19,14,9,12,12	3.1 (± 2.35)			
Week 36, n=15,13,10,12,13	1.9 (± 1.93)			
Week 40, n=15,11,9,10,10	2.6 (± 2.07)			

Week 44, n=11,11,6,8,8	3.0 (± 2.39)			
Week 48, n=9,8,5,7,5	4.0 (± 3.74)			
Week 52, n=9,5,5,5,4	1.0 (± 0.82)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Mean Health Assessment Questionnaire – Disability Index (HAQDI) Score over Time

End point title	Part A: Mean Health Assessment Questionnaire – Disability Index (HAQDI) Score over Time
End point description:	
<p>The HAQ-DI indicates the extent of the participant's functional ability during the past week, and was assessed for the subgroup of participants with symptoms of Polymyalgia Rheumatic (PMR). The HAQ-DI included 20 questions in 8 categories of functioning – dressing and grooming, arising, eating, walking, hygiene, reach, grip, and usual activities. Each functional area contains at least two questions. For each question, there is a 4-level difficulty scale that is scored from 0 to 3, representing “no difficulty” (0), “some difficulty” (1), “much difficulty” (2), and “unable to do” (3) where higher scores indicating worse disability. The score for each of the 8 category scores is taken as the maximum score given to the related questions. If no questions within a given functional area were answered, no score was provided for that category.</p>	
End point type	Secondary
End point timeframe:	
Baseline (Week 0) and Weeks 12, 24, 36 and 52	

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=19,14,13,9,12	0.6776 (± 0.65658)	1.1250 (± 0.75479)	0.9615 (± 0.84376)	0.8889 (± 0.80875)
Week 12, n=12,8,12,9,9	0.3229 (± 0.41785)	1.0938 (± 0.91063)	0.7292 (± 0.87392)	0.5694 (± 0.54526)
Week 24, n=10, 7,7,7,9	0.5875 (± 0.58940)	0.8750 (± 0.78395)	0.9821 (± 0.92823)	0.9107 (± 0.83452)
Week 36, n=6,5,4,4,7	0.5208 (± 0.70007)	0.8250 (± 0.80816)	0.6250 (± 0.51031)	0.5625 (± 0.58184)
Week 52, n=5,2,3,1,2	0.3000 (± 0.41079)	0.3125 (± 0.44194)	0.1667 (± 0.14434)	0.0000 (± 99999)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
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Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=19,14,13,9,12	0.8646 (± 0.62034)			
Week 12, n=12,8,12,9,9	0.9306 (± 0.66764)			
Week 24, n=10, 7,7,7,9	0.9583 (± 0.70986)			
Week 36, n=6,5,4,4,7	1.0000 (± 0.91287)			
Week 52, n=5,2,3,1,2	0.1875 (± 0.26517)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of participants with Patient Global Impression of Change (PGIC) Score over time

End point title	Part A: Number of participants with Patient Global Impression of Change (PGIC) Score over time
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End point description:

Patient-reported response to treatment was assessed using the PGIC measure, a single item completed by participant to provide a clinically meaningful summary of an individual's response to treatment. The assessment provides an estimate of the magnitude of treatment response at different time points during the study. Responses include: Much Better, Better, Slightly Better, No Change, Slightly Worse, Worse, and Much Worse. The categorical data of participant rating of change is summarized by treatment group, visit and response category.

End point type	Secondary
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End point timeframe:

Weeks 12, 24 and 52

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Participants				
Week 12,Much Better, n=31,28,24,22,22	11	7	2	5
Week 12,Better, n=31,28,24,22,22	11	10	11	4
Week 12, Slightly Better, n=31,28,24,22,22	3	5	4	8
Week 12,No Change, n=31,28,24,22,22	3	3	4	0
Week 12,Slightly Worse, n=31,28,24,22,22	1	1	2	4
Week 12,Worse, n=31,28,24,22,22	2	2	1	1
Week 12,Much Worse, n=31,28,24,22,22	0	0	0	0

Week 24,Much Better, n=23,20,15,17,16	11	6	6	5
Week 24,Better, n=23,20,15,17,16	7	8	4	6
Week 24, Slightly Better,n=23,20,15,17,16	2	2	0	4
Week 24,No Change, n=23,20,15,17,16	1	2	2	1
Week 24,Slightly Worse, n=23,20,15,17,16	2	1	2	1
Week 24, Worse,n=23,20,15,17,16	0	1	1	0
Week 24, Much Worse,n=23,20,15,17,16	0	0	0	0
Week 52,Much Better, n=9,5,5,5,4	6	3	3	2
Week 52,Better, n=9,5,5,5,4	2	2	1	2
Week 52,Slightly Better, n=9,5,5,5,4	0	0	1	1
Week 52,No Change, n=9,5,5,5,4	1	0	0	0
Week 52,Slightly Worse, n=9,5,5,5,4	0	0	0	0
Week 52,Worse, n=9,5,5,5,4	0	0	0	0
Week 52,Much Worse, n=9,5,5,5,4	0	0	0	0

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Participants				
Week 12,Much Better, n=31,28,24,22,22	5			
Week 12,Better, n=31,28,24,22,22	11			
Week 12, Slightly Better, n=31,28,24,22,22	3			
Week 12,No Change, n=31,28,24,22,22	3			
Week 12,Slightly Worse, n=31,28,24,22,22	0			
Week 12,Worse, n=31,28,24,22,22	0			
Week 12,Much Worse, n=31,28,24,22,22	0			
Week 24,Much Better, n=23,20,15,17,16	6			
Week 24,Better, n=23,20,15,17,16	6			
Week 24, Slightly Better,n=23,20,15,17,16	1			
Week 24,No Change, n=23,20,15,17,16	1			
Week 24,Slightly Worse, n=23,20,15,17,16	1			
Week 24, Worse,n=23,20,15,17,16	1			
Week 24, Much Worse,n=23,20,15,17,16	0			
Week 52,Much Better, n=9,5,5,5,4	3			
Week 52,Better, n=9,5,5,5,4	0			
Week 52,Slightly Better, n=9,5,5,5,4	1			
Week 52,No Change, n=9,5,5,5,4	0			
Week 52,Slightly Worse, n=9,5,5,5,4	0			
Week 52,Worse, n=9,5,5,5,4	0			

Week 52,Much Worse, n=9,5,5,5,4	0			
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Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Mean Patient Global Assessment of disease activity (PtGA) score over time

End point title	Part A: Mean Patient Global Assessment of disease activity (PtGA) score over time
End point description: The Patient's Global Assessments of Disease Activity was recorded on a Visual analog scale (VAS) of 10 centimeter (cm) ranging from 0 ("very well") to 10 ("very poor").	
End point type	Secondary
End point timeframe: Baseline (Week 0) and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52	

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,39,25,26,27	2.96 (± 2.148)	3.72 (± 2.649)	4.24 (± 2.049)	3.60 (± 2.133)
Week 2, n=38,38,25,21,27	2.59 (± 1.923)	3.51 (± 2.389)	3.73 (± 1.911)	3.45 (± 2.247)
Week 4, n=36,37,24,22,27	2.43 (± 2.138)	3.75 (± 2.770)	3.81 (± 1.737)	3.01 (± 1.997)
Week 8, n=34,30,24,21,23	1.97 (± 2.076)	3.87 (± 2.322)	3.44 (± 1.763)	2.85 (± 1.769)
Week 12, n=31,28,24,22,22	1.97 (± 1.567)	3.80 (± 2.557)	3.95 (± 2.200)	3.20 (± 2.340)
Week 16, n=27,25,22,19,19	1.95 (± 2.237)	3.82 (± 2.615)	3.39 (± 2.523)	2.86 (± 1.809)
Week 20, n=26,23,19,18,15	2.60 (± 2.089)	3.20 (± 2.663)	4.17 (± 2.334)	2.45 (± 1.697)
Week 24, n=23,20,15,17,16	2.63 (± 2.140)	2.33 (± 1.975)	3.83 (± 2.447)	2.85 (± 2.256)
Week 28, n=18,17,11,13,14	2.44 (± 2.094)	3.09 (± 2.915)	4.18 (± 2.169)	2.68 (± 2.106)
Week 32, n=19,14,9,12,12	2.01 (± 1.781)	2.22 (± 2.564)	3.02 (± 1.199)	2.43 (± 2.385)
Week 36, n=15,13,10,12,13	1.46 (± 1.253)	2.66 (± 2.982)	2.79 (± 2.013)	2.68 (± 2.490)
Week 40, n=15,11,9,10,10	2.05 (± 1.809)	2.35 (± 2.495)	3.20 (± 2.329)	2.24 (± 1.883)
Week 44, n=11,11,6,8,8	2.28 (± 2.872)	2.19 (± 2.429)	2.17 (± 1.824)	2.18 (± 1.835)
Week 48, n=9,8,5,7,5	1.81 (± 1.934)	1.03 (± 1.253)	2.30 (± 1.515)	1.86 (± 1.586)
Week 52, n=9,5,5,5,4	1.10 (± 0.857)	0.46 (± 0.358)	2.76 (± 2.668)	2.44 (± 1.716)

End point values	PartA:Placebo SC q2w + 12 month			
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	prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,39,25,26,27	3.64 (± 2.732)			
Week 2, n=38,38,25,21,27	3.52 (± 2.177)			
Week 4, n=36,37,24,22,27	2.62 (± 1.762)			
Week 8, n=34,30,24,21,23	2.90 (± 2.230)			
Week 12, n=31,28,24,22,22	2.75 (± 2.056)			
Week 16, n=27,25,22,19,19	2.76 (± 1.777)			
Week 20, n=26,23,19,18,15	2.90 (± 1.869)			
Week 24, n=23,20,15,17,16	3.34 (± 1.791)			
Week 28, n=18,17,11,13,14	2.74 (± 1.791)			
Week 32, n=19,14,9,12,12	2.88 (± 2.541)			
Week 36, n=15,13,10,12,13	2.62 (± 1.990)			
Week 40, n=15,11,9,10,10	3.00 (± 2.658)			
Week 44, n=11,11,6,8,8	3.49 (± 2.322)			
Week 48, n=9,8,5,7,5	4.48 (± 3.545)			
Week 52, n=9,5,5,5,4	2.13 (± 2.651)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Mean Physician Global Assessment of disease activity (PhGA) score over time

End point title	Part A: Mean Physician Global Assessment of disease activity (PhGA) score over time
End point description: The Physician's Global Assessments of Disease Activity was recorded on a VAS of 10 cm ranging from 0 ("none") to 10 ("extremely active").	
End point type	Secondary
End point timeframe: Baseline (Week 0) and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52	

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,39,25,26,27	2.33 (± 2.101)	2.95 (± 2.208)	2.94 (± 2.374)	3.05 (± 2.501)
Week 2, n=36,35,25,20,26	1.09 (± 1.373)	1.52 (± 1.822)	1.83 (± 1.558)	1.85 (± 1.879)
Week 4, n=33,32,23,21,25	0.81 (± 1.191)	1.44 (± 1.904)	1.55 (± 1.236)	0.92 (± 1.125)
Week 8, n=33,28,23,20,21	1.09 (± 1.508)	1.30 (± 1.723)	1.35 (± 1.229)	0.79 (± 0.798)

Week 12, n=29,25,23,18,21	1.08 (± 1.486)	1.81 (± 2.183)	1.64 (± 1.908)	1.28 (± 1.629)
Week 16, n=26,23,21,16,19	0.74 (± 0.895)	1.54 (± 1.793)	1.87 (± 2.078)	1.39 (± 1.830)
Week 20, n=25,23,18,17,15	0.71 (± 1.189)	1.42 (± 1.808)	1.16 (± 1.628)	0.83 (± 0.882)
Week 24, n=20,20,15,15,15	0.82 (± 1.089)	0.68 (± 0.869)	1.50 (± 1.690)	1.48 (± 2.003)
Week 28, n=17,17,11,12,13	0.76 (± 1.068)	1.43 (± 1.986)	1.18 (± 2.116)	0.88 (± 0.586)
Week 32, n=19,14,8,11,12	0.83 (± 1.320)	0.67 (± 0.841)	1.40 (± 1.516)	1.26 (± 1.546)
Week 36, n=13,11,10,11,13	0.48 (± 0.660)	1.12 (± 1.589)	0.61 (± 0.792)	0.56 (± 0.408)
Week 40, n=13,9,8,9,10	0.38 (± 0.395)	0.77 (± 1.417)	0.36 (± 0.283)	0.52 (± 0.531)
Week 44, n=10,9,6,8,7	0.31 (± 0.228)	1.07 (± 1.574)	0.43 (± 0.547)	0.58 (± 0.740)
Week 48, n=7,7,5,6,5	0.27 (± 0.446)	0.31 (± 0.540)	0.30 (± 0.316)	0.78 (± 1.482)
Week 52, n=9,5,5,4,4	0.31 (± 0.434)	0.10 (± 0.141)	0.32 (± 0.311)	1.35 (± 0.947)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Scores on scale				
arithmetic mean (standard deviation)				
Baseline, n=42,39,25,26,27	3.25 (± 2.823)			
Week 2, n=36,35,25,20,26	1.76 (± 2.094)			
Week 4, n=33,32,23,21,25	1.02 (± 1.090)			
Week 8, n=33,28,23,20,21	1.14 (± 1.226)			
Week 12, n=29,25,23,18,21	1.47 (± 2.151)			
Week 16, n=26,23,21,16,19	0.67 (± 0.779)			
Week 20, n=25,23,18,17,15	1.27 (± 1.622)			
Week 24, n=20,20,15,15,15	1.37 (± 1.551)			
Week 28, n=17,17,11,12,13	0.85 (± 1.440)			
Week 32, n=19,14,8,11,12	0.89 (± 1.672)			
Week 36, n=13,11,10,11,13	0.75 (± 0.906)			
Week 40, n=13,9,8,9,10	0.57 (± 0.566)			
Week 44, n=10,9,6,8,7	0.87 (± 1.404)			
Week 48, n=7,7,5,6,5	1.60 (± 2.164)			
Week 52, n=9,5,5,4,4	1.80 (± 3.082)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in serum C Reactive Protein (CRP) over time

End point title	Part A: Change from Baseline in serum C Reactive Protein (CRP) over time
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End point description:

Blood samples were collected for analysis of CRP. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for Change from Baseline in serum CRP over time for part A was reported. The Safety set comprised of all randomized participants who received at least 1 dose of SC IP.

End point type	Secondary
End point timeframe:	
Baseline (Week 0) and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52	

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Milligrams per liter				
arithmetic mean (standard deviation)				
Week 2,n=38,39,26,24,26	-5.07 (± 6.616)	-8.81 (± 22.954)	-5.15 (± 8.436)	1.27 (± 13.155)
Week 4,n=37,38,25,23,27	-4.39 (± 6.384)	-9.01 (± 23.327)	-4.09 (± 7.169)	4.91 (± 10.503)
Week 8,n=34,31,24,22,23	-4.98 (± 6.583)	-9.94 (± 25.685)	-4.19 (± 7.197)	10.00 (± 14.652)
Week 12,n=32,28,24,21,21	-5.08 (± 6.690)	-9.96 (± 26.849)	-4.22 (± 7.335)	14.81 (± 18.082)
Week 16,n=28,26,22,19,18	-4.35 (± 5.648)	-10.43 (± 27.765)	-4.48 (± 7.621)	10.53 (± 17.303)
Week 20,n=26,23,19,18,16	-4.50 (± 5.876)	-11.67 (± 29.422)	-4.78 (± 8.100)	5.32 (± 14.506)
Week 24,n=23,20,16,17,16	-4.38 (± 4.640)	-13.19 (± 31.269)	-5.14 (± 8.837)	5.07 (± 13.815)
Week 28,n=19,18,12,14,14	-5.28 (± 6.498)	-13.42 (± 33.182)	-6.33 (± 10.022)	1.87 (± 10.926)
Week 32,n=19,15,10,12,13	-4.85 (± 7.259)	-14.47 (± 36.343)	-7.15 (± 10.875)	2.61 (± 9.835)
Week 36,n=15,12,10,12,13	-4.72 (± 4.473)	-16.28 (± 40.531)	-7.08 (± 10.874)	5.73 (± 19.040)
Week 40,n=15,11,8,10,10	-4.72 (± 4.374)	-17.67 (± 42.240)	-4.69 (± 8.510)	6.27 (± 21.164)
Week 44,n=11,11,6,8,9	-5.35 (± 4.523)	-17.47 (± 42.350)	-1.90 (± 1.456)	2.80 (± 20.439)
Week 48,n=9,7,5,8,5	-5.91 (± 4.993)	-23.39 (± 52.962)	-2.20 (± 1.562)	6.31 (± 20.952)
Week 52,n=9,5,5,5,4	-6.00 (± 4.663)	-7.26 (± 9.461)	-2.20 (± 1.575)	0.64 (± 9.453)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Milligrams per liter				
arithmetic mean (standard deviation)				
Week 2,n=38,39,26,24,26	1.07 (± 6.794)			
Week 4,n=37,38,25,23,27	0.76 (± 5.511)			
Week 8,n=34,31,24,22,23	7.86 (± 25.894)			

Week 12,n=32,28,24,21,21	4.04 (± 9.339)			
Week 16,n=28,26,22,19,18	6.99 (± 15.503)			
Week 20,n=26,23,19,18,16	2.35 (± 7.840)			
Week 24,n=23,20,16,17,16	6.54 (± 20.711)			
Week 28,n=19,18,12,14,14	0.22 (± 11.318)			
Week 32,n=19,15,10,12,13	4.37 (± 16.277)			
Week 36,n=15,12,10,12,13	1.64 (± 10.418)			
Week 40,n=15,11,8,10,10	2.77 (± 13.101)			
Week 44,n=11,11,6,8,9	5.13 (± 7.292)			
Week 48,n=9,7,5,8,5	8.10 (± 18.084)			
Week 52,n=9,5,5,5,4	-1.65 (± 4.561)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in Erythrocyte Sedimentation Rate (ESR) over time

End point title	Part A: Change from Baseline in Erythrocyte Sedimentation Rate (ESR) over time
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End point description:

Blood samples were collected for analysis of ESR. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for Change from Baseline in ESR over time for part A was reported.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Millimeters per hour				
arithmetic mean (standard deviation)				
Week 2,n=37,39,26,24,26	-13.05 (± 9.885)	-12.78 (± 15.560)	-14.62 (± 16.500)	-1.33 (± 9.323)
Week 4,n=36,38,25,22,27	-12.83 (± 9.346)	-17.41 (± 15.867)	-14.13 (± 12.419)	7.59 (± 15.308)
Week 8,n=33,31,24,22,23	-14.21 (± 9.927)	-18.76 (± 17.727)	-15.05 (± 14.030)	6.41 (± 12.105)
Week 12,n=32,28,24,22,22	-14.97 (± 11.361)	-17.89 (± 17.846)	-14.30 (± 13.271)	20.36 (± 18.017)

Week 16,n=28,26,22,19,19	-12.50 (± 10.469)	-17.17 (± 17.693)	-15.37 (± 13.956)	14.21 (± 25.189)
Week 20,n=26,23,18,18,16	-13.19 (± 9.600)	-17.07 (± 18.498)	-14.33 (± 15.442)	10.00 (± 22.141)
Week 24,n=23,19,16,17,16	-13.63 (± 11.209)	-16.84 (± 15.378)	-14.89 (± 14.504)	7.59 (± 21.567)
Week 28,n=19,18,11,14,14	-15.26 (± 12.274)	-19.94 (± 20.069)	-16.84 (± 16.856)	1.50 (± 15.854)
Week 32,n=19,15,10,12,13	-13.26 (± 17.486)	-19.80 (± 19.266)	-14.52 (± 13.630)	-2.42 (± 20.129)
Week 36,n=15,12,10,12, 13	-14.47 (± 11.673)	-21.25 (± 20.855)	-14.42 (± 13.482)	0.67 (± 19.009)
Week 40,n=15,11,9,10,10	-14.40 (± 12.070)	-22.27 (± 21.873)	-11.24 (± 13.277)	9.80 (± 28.840)
Week 44,n=11,11,6,8,8	-12.64 (± 10.347)	-22.18 (± 21.409)	-12.00 (± 13.520)	4.88 (± 18.256)
Week 48,n=9,8,5,8,5	-15.33 (± 11.822)	-25.63 (± 24.372)	-14.00 (± 14.335)	4.50 (± 24.308)
Week 52,n=9,5,5,5,4	-14.78 (± 11.692)	-24.60 (± 17.700)	-12.80 (± 15.385)	-4.60 (± 10.431)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Millimeters per hour				
arithmetic mean (standard deviation)				
Week 2,n=37,39,26,24,26	-9.96 (± 20.142)			
Week 4,n=36,38,25,22,27	-5.30 (± 22.250)			
Week 8,n=33,31,24,22,23	1.78 (± 27.361)			
Week 12,n=32,28,24,22,22	-2.55 (± 21.498)			
Week 16,n=28,26,22,19,19	-2.53 (± 20.839)			
Week 20,n=26,23,18,18,16	-5.81 (± 23.063)			
Week 24,n=23,19,16,17,16	-3.06 (± 22.389)			
Week 28,n=19,18,11,14,14	-1.71 (± 29.148)			
Week 32,n=19,15,10,12,13	-2.85 (± 29.493)			
Week 36,n=15,12,10,12, 13	0.92 (± 28.324)			
Week 40,n=15,11,9,10,10	-2.60 (± 27.818)			
Week 44,n=11,11,6,8,8	2.88 (± 21.860)			
Week 48,n=9,8,5,8,5	8.60 (± 25.205)			
Week 52,n=9,5,5,5,4	1.25 (± 15.042)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of participants with adverse events (AEs), serious AEs (SAEs) and corticosteroid related AEs

End point title	Part A: Number of participants with adverse events (AEs), serious AEs (SAEs) and corticosteroid related AEs
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End point description:

An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Any untoward event resulting in death, life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, congenital anomaly/birth defect, any other situation according to medical or scientific judgment or all events of possible drug-induced liver injury with hyperbilirubinaemia were categorized as SAE. Number of participants with AEs, SAEs and corticosteroid related AEs have been reported.

End point type	Secondary
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End point timeframe:

Up to 52 weeks

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Participants				
Any AE	41	36	25	26
Any SAE	8	6	6	5
Any Corticosteroid related AE	18	21	15	13

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Participants				
Any AE	24			
Any SAE	6			
Any Corticosteroid related AE	12			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in : Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)

End point title	Part A: Change from Baseline in : Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)
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End point description:

SBP and DBP were measured in semi-supine position after 5 minutes rest at indicated time points. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Week 0), Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Millimeters of mercury				
arithmetic mean (standard deviation)				
SBP, Week 2, n=37, 39, 26, 24, 27	-0.9 (± 13.11)	3.5 (± 13.97)	-2.1 (± 17.19)	5.7 (± 12.67)
SBP, Week 4, n=37, 37, 25, 23, 27	-0.9 (± 15.17)	0.2 (± 15.99)	-4.7 (± 15.00)	-2.2 (± 14.60)
SBP, Week 8, n=34, 32, 24, 22, 23	0.3 (± 14.33)	-3.9 (± 17.17)	-3.5 (± 15.73)	-0.8 (± 18.94)
SBP, Week 12, n=32, 29, 24, 22, 22	-2.3 (± 15.19)	-2.4 (± 17.15)	-6.2 (± 13.45)	1.4 (± 12.97)
SBP, Week 16, n=28, 26, 22, 19, 19	-6.0 (± 15.39)	-5.1 (± 18.28)	-3.0 (± 20.22)	1.9 (± 17.51)
SBP, Week 20, n=26, 23, 19, 18, 16	-6.7 (± 10.73)	-0.7 (± 14.09)	-3.4 (± 15.39)	-1.7 (± 17.16)
SBP, Week 24, n=23, 21, 16, 17, 16	-5.2 (± 12.65)	-2.5 (± 15.46)	-5.6 (± 16.55)	-2.6 (± 18.75)
SBP, Week 28, n=19, 18, 12, 14, 14	-8.8 (± 12.87)	-4.2 (± 20.49)	-0.1 (± 14.76)	6.4 (± 19.31)
SBP, Week 32, n=19, 15, 10, 12, 13	-10.7 (± 13.96)	-3.7 (± 15.03)	-7.4 (± 11.80)	3.4 (± 14.99)
SBP, Week 36, n=15, 13, 10, 12, 13	-6.2 (± 13.92)	-8.0 (± 15.80)	-6.8 (± 12.10)	-0.6 (± 20.46)
SBP, Week 40, n=15, 11, 9, 10, 10	-11.9 (± 11.75)	0.9 (± 13.14)	-4.8 (± 14.17)	2.1 (± 19.31)
SBP, Week 44, n=11, 11, 6, 8, 9	-12.7 (± 17.66)	-4.2 (± 19.22)	2.7 (± 13.26)	2.9 (± 15.99)
SBP, Week 48, n=9, 8, 5, 8, 5	-13.6 (± 11.85)	-0.4 (± 9.44)	-3.6 (± 28.13)	8.8 (± 14.15)
SBP, Week 52, n=9, 5, 5, 5, 4	-8.1 (± 15.85)	1.2 (± 14.46)	2.2 (± 19.52)	2.2 (± 18.46)
DBP, Week 2, n=37, 39, 26, 24, 27	0.3 (± 7.41)	1.2 (± 10.05)	-2.3 (± 14.00)	2.4 (± 9.85)
DBP, Week 4, n=37, 37, 25, 23, 27	1.8 (± 8.85)	1.5 (± 10.24)	-4.1 (± 13.22)	0.1 (± 11.66)
DBP, Week 8, n=34, 32, 24, 22, 23	2.1 (± 8.47)	-1.3 (± 7.62)	-4.0 (± 12.26)	2.6 (± 11.27)
DBP, Week 12, n=32, 29, 24, 22, 22	1.0 (± 9.60)	2.0 (± 12.35)	-4.7 (± 12.14)	1.3 (± 10.58)

DBP,Week 16,n=28,26,22,19,19	0.2 (± 7.48)	-2.5 (± 11.58)	-3.1 (± 12.80)	-1.3 (± 10.64)
DBP,Week 20,n=26,23,19,18,16	-0.9 (± 7.66)	1.4 (± 12.47)	-3.2 (± 16.21)	-2.0 (± 9.06)
DBP,Week 24,n=23,21,16,17,16	1.3 (± 8.72)	-0.6 (± 12.85)	-2.7 (± 11.77)	-3.3 (± 10.21)
DBP,Week 28,n=19,18,12,14,14	-3.1 (± 9.39)	-2.2 (± 10.05)	-4.3 (± 15.80)	0.1 (± 13.87)
DBP,Week 32,n=19,15,10,12,13	-4.2 (± 7.50)	-2.3 (± 12.92)	-6.9 (± 25.47)	-1.2 (± 11.17)
DBP,Week 36,n=15,13,10,12,13	-0.6 (± 8.92)	-5.1 (± 9.89)	-5.6 (± 17.02)	-1.2 (± 13.31)
DBP,Week 40,n=15,11,9,10,10	-6.9 (± 12.41)	2.6 (± 11.88)	-8.0 (± 21.60)	-2.0 (± 14.07)
DBP,Week 44,n=11,11,6,8,9	-2.7 (± 12.10)	-6.5 (± 14.56)	-2.5 (± 23.89)	-1.5 (± 8.28)
DBP,Week 48,n=9,8,5,8,5	-5.6 (± 11.79)	-2.3 (± 11.42)	-2.0 (± 16.00)	-3.4 (± 12.75)
DBP,Week 52,n=9,5,5,5,4	0.2 (± 12.55)	1.8 (± 10.23)	2.2 (± 3.35)	1.4 (± 11.89)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Millimeters of mercury				
arithmetic mean (standard deviation)				
SBP,Week 2,n=37,39,26,24,27	-0.9 (± 15.63)			
SBP,Week 4,n=37,37,25,23,27	-3.4 (± 14.25)			
SBP,Week 8,n=34,32,24,22,23	-8.3 (± 21.05)			
SBP,Week 12,n=32,29,24,22,22	-6.1 (± 19.31)			
SBP,Week 16,n=28,26,22,19,19	-6.4 (± 12.73)			
SBP,Week 20,n=26,23,19,18,16	-9.4 (± 21.44)			
SBP,Week 24,n=23,21,16,17,16	-8.6 (± 15.65)			
SBP,Week 28,n=19,18,12,14,14	-2.6 (± 17.71)			
SBP,Week 32,n=19,15,10,12,13	-8.8 (± 14.80)			
SBP,Week 36,n=15,13,10,12,13	-2.5 (± 16.13)			
SBP,Week 40,n=15,11,9,10,10	-7.4 (± 20.14)			
SBP,Week 44,n=11,11,6,8,9	1.8 (± 13.91)			
SBP,Week 48,n=9,8,5,8,5	4.8 (± 15.51)			
SBP,Week 52,n=9,5,5,5,4	-3.8 (± 12.34)			
DBP,Week 2,n=37,39,26,24,27	-2.2 (± 9.22)			
DBP,Week 4,n=37,37,25,23,27	-3.0 (± 10.22)			
DBP,Week 8,n=34,32,24,22,23	-5.6 (± 11.83)			
DBP,Week 12,n=32,29,24,22,22	-2.5 (± 11.16)			
DBP,Week 16,n=28,26,22,19,19	-3.4 (± 7.97)			
DBP,Week 20,n=26,23,19,18,16	-2.1 (± 10.98)			
DBP,Week 24,n=23,21,16,17,16	-3.1 (± 9.27)			
DBP,Week 28,n=19,18,12,14,14	-1.9 (± 10.37)			
DBP,Week 32,n=19,15,10,12,13	-5.8 (± 9.09)			
DBP,Week 36,n=15,13,10,12,13	-2.7 (± 13.05)			
DBP,Week 40,n=15,11,9,10,10	-6.1 (± 11.97)			
DBP,Week 44,n=11,11,6,8,9	1.3 (± 11.36)			
DBP,Week 48,n=9,8,5,8,5	0.6 (± 8.47)			
DBP,Week 52,n=9,5,5,5,4	0.5 (± 5.92)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in Pulse Rate

End point title	Part A: Change from Baseline in Pulse Rate
End point description:	
Pulse rate was measured in semi-supine position after 5 minutes rest at Baseline and up to 52 weeks. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.	
End point type	Secondary
End point timeframe:	
Baseline (Week 0) and Weeks 2, 4 ,8,12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52	

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Beats per minute				
arithmetic mean (standard deviation)				
Week 2, ,n=37,39,25,24,27	-1.9 (± 8.07)	-2.1 (± 8.93)	1.8 (± 10.40)	-0.4 (± 12.34)
Week 4,n=37,37,25,22,27	0.2 (± 8.82)	-1.4 (± 8.94)	-2.4 (± 9.42)	2.2 (± 13.39)
Week 8,n=34,32,24,22,23	-1.1 (± 10.23)	-3.2 (± 11.42)	-3.1 (± 8.80)	4.3 (± 12.36)
Week 12,n=32,29,23,22,22	-3.8 (± 8.50)	-1.2 (± 13.62)	-0.8 (± 8.35)	4.5 (± 14.54)
Week 16,n=28,26,22,19,19	-3.4 (± 10.79)	0.3 (± 9.06)	-5.3 (± 10.32)	0.3 (± 15.04)
Week 20,n=26,23,19,18,16	-3.0 (± 9.75)	0.2 (± 11.35)	-0.7 (± 12.62)	1.0 (± 13.76)
Week 24,n=23,21,16,17,16	-2.1 (± 9.29)	-3.5 (± 11.18)	0.7 (± 14.13)	0.1 (± 12.76)
Week 28,n=19,18,12,14,14	-1.4 (± 10.33)	-1.2 (± 9.21)	-3.5 (± 13.26)	0.1 (± 13.24)
Week 32,n=19,15,10,12,13	-1.3 (± 8.20)	-4.7 (± 8.50)	-2.2 (± 10.78)	-0.8 (± 16.10)
Week 36,n=15,13,10,12,13	-5.9 (± 9.79)	-5.1 (± 9.06)	-4.5 (± 9.12)	-0.5 (± 12.22)
Week 40,n=15,11,9,10,10	-3.9 (± 5.64)	-3.0 (± 11.93)	-3.4 (± 10.57)	3.3 (± 12.83)
Week 44,n=11,11,6,8,9	-7.1 (± 8.01)	-3.4 (± 15.86)	-8.3 (± 13.41)	4.3 (± 15.34)
Week 48,n=9,8,5,8,5	-8.2 (± 7.36)	-9.3 (± 8.76)	-7.2 (± 10.47)	-1.9 (± 11.47)
Week 52,n=9,5,5,5,4	-5.0 (± 12.97)	-11.0 (± 3.74)	-4.0 (± 15.89)	6.8 (± 6.34)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
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Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Beats per minute				
arithmetic mean (standard deviation)				
Week 2, ,n=37,39,25,24,27	-1.6 (± 9.79)			
Week 4,n=37,37,25,22,27	-1.9 (± 10.33)			
Week 8,n=34,32,24,22,23	0.5 (± 11.06)			
Week 12,n=32,29,23,22,22	-2.7 (± 10.95)			
Week 16,n=28,26,22,19,19	-2.2 (± 10.76)			
Week 20,n=26,23,19,18,16	-4.0 (± 12.54)			
Week 24,n=23,21,16,17,16	2.7 (± 8.27)			
Week 28,n=19,18,12,14,14	0.5 (± 10.60)			
Week 32,n=19,15,10,12,13	-0.6 (± 12.58)			
Week 36,n=15,13,10,12,13	-3.2 (± 9.83)			
Week 40,n=15,11,9,10,10	-3.8 (± 14.09)			
Week 44,n=11,11,6,8,9	-3.4 (± 8.57)			
Week 48,n=9,8,5,8,5	0.0 (± 16.72)			
Week 52,n=9,5,5,5,4	-5.3 (± 12.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in Temperature

End point title	Part A: Change from Baseline in Temperature
End point description:	Temperature was measured in semi-supine position after 5 minutes rest at Baseline and up to 52 weeks. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.
End point type	Secondary
End point timeframe:	Baseline (Week 0) and Weeks 2, 4 ,8,12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52

End point values	PartA:SIR 100 mg SC q2w+6 month prednisone	PartA:SIR 100 mg SC q2w+3 month prednisone	PartA:SIR 50 mg SC q4w+6 month prednisone	PartA:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Celsius				
arithmetic mean (standard deviation)				
Week 2, ,n=37,39,26,24,27	-0.11 (± 0.269)	-0.04 (± 0.336)	0.03 (± 0.433)	-0.16 (± 0.421)
Week 4,n=37,37,25,23,27	-0.12 (± 0.345)	0.01 (± 0.407)	0.04 (± 0.399)	-0.10 (± 0.387)
Week 8,n=34,32,23,22,23	-0.04 (± 0.400)	-0.09 (± 0.432)	-0.07 (± 0.553)	0.04 (± 0.579)
Week 12,n=32,29,24,22,22	-0.08 (± 0.461)	-0.11 (± 0.367)	0.01 (± 0.444)	-0.15 (± 0.494)

Week 16,n=28,26,22,19,19	-0.08 (± 0.313)	-0.05 (± 0.392)	0.04 (± 0.316)	-0.21 (± 0.664)
Week 20,n=26,23,19,18,16	0.03 (± 0.428)	-0.05 (± 0.483)	-0.12 (± 0.651)	-0.07 (± 0.355)
Week 24,n=23,21,16,17,16	0.03 (± 0.389)	-0.11 (± 0.255)	-0.11 (± 0.558)	-0.26 (± 0.476)
Week 28,n=19,18,12,13,14	0.03 (± 0.444)	-0.07 (± 0.517)	-0.09 (± 0.683)	-0.16 (± 0.479)
Week 32,n=19,15,10,12,13	-0.01 (± 0.515)	-0.07 (± 0.349)	0.28 (± 0.418)	-0.13 (± 0.367)
Week 36,n=15,13,9,12,13	-0.09 (± 0.406)	-0.11 (± 0.569)	-0.10 (± 0.391)	-0.09 (± 0.390)
Week 40,n=15,11,9,10,10	0.08 (± 0.426)	-0.03 (± 0.454)	0.18 (± 0.438)	-0.05 (± 0.334)
Week 44,n=11,11,6,8,9	-0.14 (± 0.347)	-0.06 (± 0.391)	-0.03 (± 0.314)	0.00 (± 0.438)
Week 48,n=9,8,5,8,5	-0.22 (± 0.233)	-0.05 (± 0.510)	-0.14 (± 0.498)	-0.01 (± 0.280)
Week 52,n=9,5,5,5,4	-0.08 (± 0.291)	-0.32 (± 0.286)	0.14 (± 0.230)	0.02 (± 0.409)

End point values	PartA:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Celsius				
arithmetic mean (standard deviation)				
Week 2, ,n=37,39,26,24,27	0.10 (± 0.449)			
Week 4,n=37,37,25,23,27	0.11 (± 0.340)			
Week 8,n=34,32,23,22,23	0.19 (± 0.425)			
Week 12,n=32,29,24,22,22	0.09 (± 0.450)			
Week 16,n=28,26,22,19,19	0.09 (± 0.317)			
Week 20,n=26,23,19,18,16	0.05 (± 0.395)			
Week 24,n=23,21,16,17,16	0.04 (± 0.441)			
Week 28,n=19,18,12,13,14	-0.06 (± 0.282)			
Week 32,n=19,15,10,12,13	0.01 (± 0.364)			
Week 36,n=15,13,9,12,13	-0.08 (± 0.367)			
Week 40,n=15,11,9,10,10	-0.05 (± 0.306)			
Week 44,n=11,11,6,8,9	-0.08 (± 0.396)			
Week 48,n=9,8,5,8,5	-0.08 (± 0.559)			
Week 52,n=9,5,5,5,4	-0.08 (± 0.814)			

Statistical analyses

Secondary: Part A: Change from Baseline in hematology parameters- Eosinophils, Leukocytes, Lymphocytes, Neutrophils and Platelets

End point title	Part A: Change from Baseline in hematology parameters- Eosinophils, Leukocytes, Lymphocytes, Neutrophils and Platelets
End point description:	
Blood samples were collected to analyze the hematology parameters including Eosinophils, Leukocytes, Lymphocytes, Neutrophils and Platelets. Change from Baseline is presented for these parameters. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.	
End point type	Secondary
End point timeframe:	
Baseline (Week 0) and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52	

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Giga cells per liter				
arithmetic mean (standard deviation)				
Eosinophils, Week 2, n=37, 36, 24, 23, 25	0.019 (± 0.0543)	0.001 (± 0.0690)	0.010 (± 0.0433)	0.015 (± 0.0557)
Eosinophils, Week 4, n=36, 37, 24, 22, 26	0.043 (± 0.0934)	0.035 (± 0.1238)	0.012 (± 0.0719)	0.023 (± 0.0617)
Eosinophils, Week 8, n=34, 29, 22, 22, 21	0.056 (± 0.0959)	0.102 (± 0.1634)	0.054 (± 0.1036)	0.048 (± 0.1498)
Eosinophils, Week 12, n=31, 28, 23, 22, 22	0.077 (± 0.1128)	0.155 (± 0.1971)	0.090 (± 0.0860)	0.090 (± 0.1684)
Eosinophils, Week 16, n=27, 26, 20, 19, 19	0.097 (± 0.1307)	0.162 (± 0.2170)	0.117 (± 0.1772)	0.067 (± 0.1148)
Eosinophils, Week 20, n=25, 22, 18, 17, 16	0.166 (± 0.2073)	0.114 (± 0.2085)	0.136 (± 0.1518)	0.094 (± 0.1743)
Eosinophils, Week 24, n=22, 21, 16, 16, 16	0.210 (± 0.4418)	0.109 (± 0.1590)	0.109 (± 0.1094)	0.089 (± 0.2392)
Eosinophils, Week 28, n=18, 18, 11, 14, 13	0.163 (± 0.2562)	0.068 (± 0.1340)	0.120 (± 0.1340)	0.046 (± 0.0714)
Eosinophils, Week 32, n=19, 15, 10, 12, 13	0.244 (± 0.3707)	0.069 (± 0.1580)	0.092 (± 0.1253)	0.038 (± 0.0597)
Eosinophils, Week 36, n=15, 12, 10, 12, 12	0.282 (± 0.3117)	0.076 (± 0.1753)	0.153 (± 0.1166)	0.049 (± 0.0720)
Eosinophils, Week 40, n=14, 11, 8, 10, 10	0.191 (± 0.2175)	0.075 (± 0.1924)	0.104 (± 0.1161)	0.065 (± 0.0737)
Eosinophils, Week 44, n=11, 10, 6, 7, 9	0.144 (± 0.1952)	0.045 (± 0.1329)	0.165 (± 0.1564)	0.024 (± 0.0541)
Eosinophils, Week 48, n=9, 8, 4, 8, 5	0.091 (± 0.0664)	0.059 (± 0.1561)	0.233 (± 0.2387)	0.028 (± 0.0489)
Eosinophils, Week 52, n=8, 5, 5, 5, 4	0.151 (± 0.1865)	0.192 (± 0.1839)	0.172 (± 0.1207)	0.108 (± 0.1139)
Leukocytes, Week 2, n=37, 38, 24, 24, 25	-3.12 (± 2.268)	-3.63 (± 1.971)	-3.32 (± 2.816)	-0.76 (± 2.145)
Leukocytes, Week 4, n=36, 37, 24, 22, 26	-3.66 (± 2.621)	-4.76 (± 2.411)	-4.07 (± 2.157)	-1.64 (± 2.247)

Leukocytes, Week 8, n=34, 29, 23, 22, 21	-4.04 (± 2.481)	-5.65 (± 3.672)	-4.42 (± 2.469)	-1.79 (± 2.682)
Leukocytes, Week 12, n=31, 28, 23, 22, 22	-4.68 (± 2.666)	-5.67 (± 2.551)	-5.23 (± 2.581)	-2.66 (± 2.883)
Leukocytes, Week 16, n=27, 26, 20, 19, 19	-5.21 (± 2.244)	-5.61 (± 3.502)	-5.36 (± 2.309)	-2.98 (± 3.018)
Leukocytes, Week 20, n=25, 23, 18, 18, 16	-5.24 (± 1.950)	-5.20 (± 3.104)	-5.40 (± 2.414)	-3.24 (± 3.592)
Leukocytes, Week 24, n=22, 21, 16, 16, 16	-5.14 (± 3.559)	-6.39 (± 2.952)	-5.01 (± 1.884)	-2.89 (± 3.892)
Leukocytes, Week 28, n=18, 18, 12, 14, 13	-5.46 (± 2.619)	-6.04 (± 3.274)	-4.58 (± 2.143)	-3.01 (± 3.368)
Leukocytes, Week 32, n=19, 15, 10, 12, 13	-5.71 (± 2.419)	-5.61 (± 3.250)	-5.27 (± 1.696)	-3.43 (± 3.342)
Leukocytes, Week 36, n=15, 12, 10, 12, 12	-5.76 (± 2.106)	-6.82 (± 2.814)	-5.58 (± 1.757)	-3.36 (± 3.612)
Leukocytes, Week 40, n=14, 11, 8, 10, 10	-6.14 (± 1.987)	-7.10 (± 2.534)	-6.46 (± 2.130)	-3.18 (± 3.662)
Leukocytes, Week 44, n=11, 10, 6, 7, 9	-6.25 (± 2.300)	-6.95 (± 2.441)	-6.17 (± 1.726)	-2.83 (± 3.875)
Leukocytes, Week 48, n=9, 8, 4, 8, 5	-6.88 (± 2.436)	-7.35 (± 2.853)	-6.48 (± 2.887)	-2.69 (± 2.979)
Leukocytes, Week 52, n=8, 5, 5, 5, 4	-6.66 (± 2.654)	-7.36 (± 2.920)	-6.38 (± 2.262)	-3.84 (± 3.467)
Lymphocytes, Week 2, n=37, 36, 24, 23, 25	0.015 (± 1.1645)	0.002 (± 1.2620)	-0.041 (± 1.3241)	-0.159 (± 0.9064)
Lymphocytes, Week 4, n=36, 37, 24, 22, 26	0.027 (± 1.2460)	-0.255 (± 1.2225)	0.057 (± 1.2338)	-0.002 (± 0.7340)
Lymphocytes, Week 8, n=34, 29, 22, 22, 21	-0.191 (± 1.3361)	-0.411 (± 1.2086)	-0.067 (± 1.2814)	-0.049 (± 1.0832)
Lymphocytes, Week 12, n=31, 28, 23, 22, 22	-0.215 (± 1.3052)	-0.437 (± 1.2479)	-0.081 (± 1.2018)	-0.128 (± 1.0505)
Lymphocytes, Week 16, n=27, 26, 20, 19, 19	-0.450 (± 1.3450)	-0.704 (± 1.2994)	-0.153 (± 0.7804)	-0.327 (± 1.4269)
Lymphocytes, Week 20, n=25, 22, 18, 17, 16	-0.616 (± 1.2793)	-0.313 (± 1.3011)	-0.439 (± 1.4363)	-0.385 (± 0.8819)
Lymphocytes, Week 24, n=22, 21, 16, 16, 16	-0.399 (± 1.4276)	-0.179 (± 1.8386)	-0.073 (± 0.7890)	-0.401 (± 1.2030)
Lymphocytes, Week 28, n=18, 18, 11, 14, 13	-0.614 (± 1.5450)	-0.273 (± 1.3296)	-0.192 (± 0.7271)	-0.258 (± 1.0211)
Lymphocytes, Week 32, n=19, 15, 10, 12, 13	-0.602 (± 1.3438)	-0.407 (± 1.4002)	-0.476 (± 0.7997)	-0.402 (± 1.2625)
Lymphocytes, Week 36, n=15, 12, 10, 12, 12	-0.625 (± 1.5738)	-0.672 (± 1.2263)	-0.430 (± 0.7690)	-0.417 (± 1.0538)
Lymphocytes, Week 40, n=14, 11, 8, 10, 10	-0.929 (± 1.5351)	-0.845 (± 1.3603)	-0.570 (± 0.8261)	-0.519 (± 1.1491)
Lymphocytes, Week 44, n=11, 10, 6, 7, 9	-0.915 (± 1.2235)	-1.047 (± 1.3375)	-0.198 (± 0.9783)	-1.029 (± 1.0293)
Lymphocytes, Week 48, n=9, 8, 4, 8, 5	-1.258 (± 1.2063)	-0.923 (± 1.4811)	0.118 (± 1.0588)	-0.576 (± 1.1994)
Lymphocytes, Week 52, n=8, 5, 5, 5, 4	-1.253 (± 1.2857)	-0.754 (± 1.0291)	-0.286 (± 1.0455)	0.194 (± 0.8800)
Neutrophils, Week 2, n=37, 36, 24, 23, 25	-3.208 (± 2.5761)	-3.454 (± 2.2265)	-3.367 (± 2.5781)	-0.748 (± 2.2688)
Neutrophils, Week 4, n=36, 37, 24, 22, 26	-3.791 (± 2.5242)	-4.476 (± 2.3632)	-4.106 (± 2.4354)	-1.673 (± 1.9745)
Neutrophils, Week 8, n=34, 29, 22, 22, 21	-3.949 (± 2.5477)	-5.271 (± 3.2214)	-4.354 (± 2.4128)	-1.869 (± 3.2525)
Neutrophils, Week 12, n=31, 28, 23, 22, 22	-4.590 (± 2.6603)	-5.340 (± 2.6437)	-5.250 (± 2.1872)	-2.678 (± 3.1106)
Neutrophils, Week 16, n=27, 26, 20, 19, 19	-4.933 (± 2.4430)	-4.929 (± 3.7907)	-5.358 (± 2.2367)	-2.766 (± 3.3212)

Neutrophils, Week 20, n=25, 22, 18, 17, 16	-4.867 (± 2.3110)	-4.997 (± 3.0763)	-5.168 (± 2.4898)	-2.856 (± 4.0311)
Neutrophils, Week 24, n=22, 21, 16, 16, 16	-4.985 (± 3.5051)	-6.257 (± 2.7551)	-5.030 (± 1.9579)	-2.570 (± 4.2089)
Neutrophils, Week 28, n=18, 18, 11, 14, 13	-5.076 (± 2.3415)	-5.729 (± 3.1699)	-4.469 (± 2.1333)	-2.764 (± 3.5787)
Neutrophils, Week 32, n=19, 15, 10, 12, 13	-5.357 (± 2.5525)	-5.153 (± 3.1939)	-4.840 (± 1.9387)	-3.006 (± 3.7915)
Neutrophils, Week 36, n=15, 12, 10, 12, 12	-5.444 (± 2.1894)	-6.079 (± 3.0406)	-5.265 (± 1.8375)	-3.023 (± 3.9443)
Neutrophils, Week 40, n=14, 11, 8, 10, 10	-5.416 (± 2.4371)	-6.179 (± 2.8859)	-5.916 (± 1.7172)	-2.705 (± 3.4469)
Neutrophils, Week 44, n=11, 10, 6, 7, 9	-5.432 (± 2.5555)	-5.799 (± 3.1785)	-6.185 (± 1.3944)	-1.807 (± 4.5472)
Neutrophils, Week 48, n=9, 8, 4, 8, 5	-5.628 (± 2.3471)	-6.396 (± 3.4832)	-6.790 (± 1.6060)	-2.160 (± 3.3843)
Neutrophils, Week 52, n=8, 5, 5, 5, 4	-5.520 (± 2.7316)	-6.774 (± 2.6817)	-6.256 (± 1.8929)	-4.214 (± 3.6948)
Platelets, Week 2, n=37, 38, 24, 23, 25	-39.0 (± 39.46)	-49.2 (± 52.77)	-41.1 (± 40.29)	-1.9 (± 37.57)
Platelets, Week 4, n=36, 37, 24, 22, 26	-45.9 (± 41.70)	-64.3 (± 56.21)	-49.0 (± 35.74)	2.1 (± 41.23)
Platelets, Week 8, n=34, 29, 22, 22, 21	-37.3 (± 31.22)	-72.2 (± 75.77)	-53.3 (± 37.10)	14.2 (± 45.62)
Platelets, Week 12, n=31, 28, 23, 22, 22	-51.2 (± 33.25)	-74.0 (± 52.17)	-55.4 (± 38.89)	17.8 (± 50.58)
Platelets, Week 16, n=27, 26, 20, 19, 19	-53.8 (± 33.54)	-69.9 (± 53.79)	-54.8 (± 39.71)	12.4 (± 52.98)
Platelets, Week 20, n=25, 22, 18, 17, 16	-52.2 (± 54.64)	-69.5 (± 58.27)	-53.5 (± 38.00)	14.8 (± 44.55)
Platelets, Week 24, n=22, 21, 16, 16, 16	-58.0 (± 39.58)	-72.4 (± 64.56)	-57.5 (± 44.46)	6.3 (± 46.94)
Platelets, Week 28, n=18, 18, 11, 14, 13	-70.2 (± 45.09)	-61.3 (± 54.34)	-50.6 (± 27.71)	15.4 (± 31.84)
Platelets, Week 32, n=19, 15, 10, 12, 13	-57.6 (± 66.52)	-65.5 (± 51.20)	-50.8 (± 33.70)	-1.5 (± 45.26)
Platelets, Week 36, n=15, 12, 10, 12, 12	-74.1 (± 32.84)	-70.6 (± 58.49)	-48.6 (± 23.64)	13.4 (± 32.69)
Platelets, Week 40, n=14, 11, 8, 10, 10	-77.4 (± 41.72)	-66.9 (± 62.21)	-42.0 (± 21.33)	5.6 (± 45.38)
Platelets, Week 44, n=11, 10, 6, 7, 9	-69.5 (± 36.62)	-76.7 (± 64.91)	-58.2 (± 19.28)	11.1 (± 48.18)
Platelets, Week 48, n=9, 8, 4, 8, 5	-68.3 (± 41.94)	-71.4 (± 57.71)	-80.8 (± 22.98)	14.4 (± 53.59)
Platelets, Week 52, n=8, 5, 5, 5, 4	-81.9 (± 38.36)	-51.6 (± 43.90)	-58.6 (± 40.79)	-18.6 (± 55.44)

End point values	PartA: Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Giga cells per liter				
arithmetic mean (standard deviation)				
Eosinophils, Week 2, n=37, 36, 24, 23, 25	0.062 (± 0.2084)			

Eosinophils, Week 4, n=36,37,24,22,26	0.030 (± 0.1164)			
Eosinophils, Week 8, n=34,29,22,22,21	0.010 (± 0.0591)			
Eosinophils, Week 12, n=31,28,23,22,22	0.030 (± 0.0548)			
Eosinophils, Week 16, n=27,26,20,19,19	0.067 (± 0.1746)			
Eosinophils, Week 20, n=25,22,18,17,16	0.057 (± 0.0637)			
Eosinophils, Week 24, n=22,21,16,16,16	0.051 (± 0.0676)			
Eosinophils, Week 28, n=18,18,11,14,13	0.051 (± 0.0538)			
Eosinophils, Week 32, n=19,15,10,12,13	0.056 (± 0.0733)			
Eosinophils, Week 36, n=15,12,10,12,12	0.059 (± 0.0585)			
Eosinophils, Week 40, n=14,11,8,10,10	0.071 (± 0.1140)			
Eosinophils, Week 44, n=11,10,6,7,9	0.066 (± 0.0600)			
Eosinophils, Week 48, n=9,8,4,8,5	0.030 (± 0.0604)			
Eosinophils, Week 52, n=8,5,5,5,4	0.013 (± 0.0802)			
Leukocytes, Week 2, n=37,38,24,24,25	0.34 (± 2.238)			
Leukocytes, Week 4, n=36,37,24,22,26	-0.16 (± 2.330)			
Leukocytes, Week 8, n=34,29,23,22,21	-0.26 (± 1.880)			
Leukocytes, Week 12, n=31,28,23,22,22	-1.28 (± 1.810)			
Leukocytes, Week 16, n=27,26,20,19,19	-0.79 (± 3.018)			
Leukocytes, Week 20, n=25,23,18,18,16	-1.71 (± 2.840)			
Leukocytes, Week 24, n=22,21,16,16,16	-1.52 (± 2.738)			
Leukocytes, Week 28, n=18,18,12,14,13	-1.97 (± 3.461)			
Leukocytes, Week 32, n=19,15,10,12,13	-2.33 (± 3.011)			
Leukocytes, Week 36, n=15,12,10,12,12	-2.95 (± 3.635)			
Leukocytes, Week 40, n=14,11,8,10,10	-2.23 (± 3.142)			
Leukocytes, Week 44, n=11,10,6,7,9	-3.08 (± 3.056)			
Leukocytes, Week 48, n=9,8,4,8,5	-3.00 (± 3.045)			
Leukocytes, Week 52, n=8,5,5,5,4	-3.10 (± 4.090)			
Lymphocytes, Week 2, n=37,36,24,23,25	-0.209 (± 0.9381)			
Lymphocytes, Week 4, n=36,37,24,22,26	-0.382 (± 1.0808)			
Lymphocytes, Week 8, n=34,29,22,22,21	-0.516 (± 0.8562)			
Lymphocytes, Week 12, n=31,28,23,22,22	-0.344 (± 0.7846)			

Lymphocytes,Week 16,n=27,26,20,19,19	-0.635 (± 0.8037)			
Lymphocytes,Week 20,n=25,22,18,17,16	-0.533 (± 0.7432)			
Lymphocytes,Week 24,n=22,21,16,16,16	-0.386 (± 0.7504)			
Lymphocytes,Week 28,n=18,18,11,14,13	-0.565 (± 1.0397)			
Lymphocytes,Week 32,n=19,15,10,12,13	-0.492 (± 0.7877)			
Lymphocytes,Week 36,n=15,12,10,12,12	-0.078 (± 0.7182)			
Lymphocytes,Week 40,n=14,11,8,10,10	-0.681 (± 0.7363)			
Lymphocytes,Week 44,n=11,10,6,7,9	-0.343 (± 0.8113)			
Lymphocytes,Week 48,n=9,8,4,8,5	-0.510 (± 1.1450)			
Lymphocytes,Week 52,n=8,5,5,5,4	-0.128 (± 1.2618)			
Neutrophils,Week 2,n=37,36,24,23,25	0.387 (± 2.6156)			
Neutrophils,Week 4,n=36,37,24,22,26	0.089 (± 3.1611)			
Neutrophils,Week 8,n=34,29,22,22,21	0.192 (± 2.2180)			
Neutrophils,Week 12,n=31,28,23,22,22	-1.019 (± 2.1306)			
Neutrophils,Week 16,n=27,26,20,19,19	-0.263 (± 3.3610)			
Neutrophils,Week 20,n=25,22,18,17,16	-1.355 (± 3.3883)			
Neutrophils,Week 24,n=22,21,16,16,16	-1.342 (± 3.1038)			
Neutrophils,Week 28,n=18,18,11,14,13	-1.503 (± 4.3502)			
Neutrophils,Week 32,n=19,15,10,12,13	-2.018 (± 3.5674)			
Neutrophils,Week 36,n=15,12,10,12,12	-3.018 (± 4.1223)			
Neutrophils,Week 40,n=14,11,8,10,10	-1.663 (± 3.4090)			
Neutrophils,Week 44,n=11,10,6,7,9	-2.883 (± 3.8690)			
Neutrophils,Week 48,n=9,8,4,8,5	-2.650 (± 4.0017)			
Neutrophils,Week 52,n=8,5,5,5,4	-2.990 (± 4.8629)			
Platelets,Week 2,n=37,38,24,23,25	-4.3 (± 49.32)			
Platelets,Week 4,n=36,37,24,22,26	-5.7 (± 43.51)			
Platelets,Week 8,n=34,29,22,22,21	15.7 (± 57.21)			
Platelets,Week 12,n=31,28,23,22,22	4.3 (± 55.14)			
Platelets,Week 16,n=27,26,20,19,19	13.8 (± 60.11)			
Platelets,Week 20,n=25,22,18,17,16	-0.1 (± 56.21)			
Platelets,Week 24,n=22,21,16,16,16	20.1 (± 45.30)			
Platelets,Week 28,n=18,18,11,14,13	13.1 (± 47.56)			
Platelets,Week 32,n=19,15,10,12,13	10.7 (± 53.95)			
Platelets,Week 36,n=15,12,10,12,12	20.0 (± 85.28)			
Platelets,Week 40,n=14,11,8,10,10	5.3 (± 54.71)			
Platelets,Week 44,n=11,10,6,7,9	-3.3 (± 56.78)			

Platelets,Week 48,n=9,8,4,8,5	0.4 (± 61.59)			
Platelets,Week 52,n=8,5,5,5,4	-17.5 (± 38.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in hematology parameters- Mean Corpuscular Hemoglobin Concentration (MCHC) and Hemoglobin

End point title	Part A: Change from Baseline in hematology parameters- Mean Corpuscular Hemoglobin Concentration (MCHC) and Hemoglobin
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End point description:

Blood samples were collected to analyze the hematology parameters including MCHC and Hemoglobin. Change from Baseline is presented for these parameters. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Grams per liter				
arithmetic mean (standard deviation)				
MCHC,Week 2,n=32,33,18,22,23	-0.5 (± 6.21)	0.1 (± 9.47)	1.9 (± 5.11)	-1.1 (± 6.56)
MCHC,Week 4,n=31,31,19,20,25	1.6 (± 7.36)	2.3 (± 11.94)	2.6 (± 9.46)	0.1 (± 5.17)
MCHC,Week 8,n=28,24,18,20,20	6.1 (± 8.97)	6.7 (± 10.98)	6.4 (± 9.09)	0.6 (± 9.53)
MCHC,Week 12,n=25,23,18,20,20	6.5 (± 9.77)	6.7 (± 9.03)	5.9 (± 14.20)	1.3 (± 9.55)
MCHC,Week 16,n=22,21,17,17,17	8.3 (± 9.80)	8.9 (± 12.41)	10.2 (± 8.50)	0.9 (± 11.52)
MCHC,Week 20,n=19,18,14,16,14	7.7 (± 8.43)	10.8 (± 9.53)	9.0 (± 8.60)	3.4 (± 10.38)
MCHC,Week 24,n=16,16,13,15,14	4.7 (± 7.50)	14.6 (± 11.04)	4.9 (± 9.97)	3.0 (± 7.46)
MCHC,Week 28,n=13,14,10,12,11	4.5 (± 7.78)	9.2 (± 11.52)	8.9 (± 11.41)	2.8 (± 13.57)
MCHC,Week 32,n=13,11,8,10,11	6.9 (± 9.33)	8.4 (± 10.45)	8.8 (± 9.05)	6.7 (± 8.88)
MCHC,Week 36,n=10,10,8,10,10	6.9 (± 5.11)	6.7 (± 9.72)	13.5 (± 8.07)	7.9 (± 11.44)
MCHC,Week 40,n=10,9,7,8,9	11.5 (± 9.89)	11.3 (± 7.75)	14.4 (± 12.45)	5.1 (± 15.30)
MCHC,Week 44,n=8,8,4,5,8	12.5 (± 7.17)	9.9 (± 9.86)	13.5 (± 4.12)	5.2 (± 4.60)
MCHC,Week 48,n=6,7,2,6,4	13.3 (± 9.07)	11.9 (± 9.84)	10.5 (± 13.44)	3.8 (± 11.48)
MCHC,Week 52,n=6,4,3,4,3	16.5 (± 5.47)	18.8 (± 5.68)	24.0 (± 3.46)	11.3 (± 5.06)
Hemoglobin,Week 2,n=38,39,24,24,25	1.2 (± 6.50)	2.5 (± 6.85)	1.3 (± 8.72)	-2.4 (± 7.08)
Hemoglobin,Week 4,n=36,37,24,22,27	3.0 (± 6.37)	2.8 (± 8.17)	2.5 (± 6.55)	-1.0 (± 8.45)
Hemoglobin,Week 8,n=34,29,23,22,21	5.9 (± 9.57)	4.7 (± 9.59)	3.1 (± 7.00)	-1.4 (± 10.54)
Hemoglobin,Week 12,n=31,28,23,22,22	5.8 (± 7.85)	8.4 (± 10.62)	4.7 (± 6.24)	-3.2 (± 11.11)
Hemoglobin,Week 16,n=27,26,21,19,19	2.6 (± 6.00)	5.8 (± 8.87)	4.2 (± 7.03)	-3.8 (± 10.55)

Hemoglobin,Week 20,n=25,23,18,18,16	2.0 (± 7.89)	7.4 (± 9.69)	3.3 (± 5.58)	-4.6 (± 11.32)
Hemoglobin,Week 24,n=22,21,16,16,16	2.2 (± 8.67)	7.0 (± 9.99)	5.4 (± 6.38)	-3.1 (± 12.05)
Hemoglobin,Week 28,n=18,18,12,14,13	0.3 (± 9.68)	5.8 (± 11.83)	2.8 (± 6.92)	-4.4 (± 11.45)
Hemoglobin,Week 32,n=19,15,10,12,13	0.9 (± 9.04)	5.1 (± 10.88)	2.0 (± 9.42)	-3.0 (± 10.05)
Hemoglobin,Week 36,n=15,12,10,12,12	4.4 (± 7.97)	4.8 (± 11.91)	4.0 (± 7.26)	-2.6 (± 10.93)
Hemoglobin,Week 40,n=14,11,8,10,10	1.3 (± 8.03)	3.8 (± 12.40)	6.3 (± 5.47)	-3.4 (± 11.24)
Hemoglobin,Week 44,n=11,10,6,8,9	0.0 (± 8.00)	6.7 (± 14.60)	2.3 (± 7.84)	-0.3 (± 11.70)
Hemoglobin,Week 48,n=9,8,4,8,5	2.4 (± 7.57)	4.8 (± 12.62)	2.8 (± 12.69)	-4.6 (± 14.66)
Hemoglobin,Week 52,n=8,5,5,5,4	2.9 (± 5.33)	8.6 (± 12.84)	10.4 (± 13.28)	4.4 (± 6.47)

End point values	PartA:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Grams per liter				
arithmetic mean (standard deviation)				
MCHC,Week 2,n=32,33,18,22,23	1.2 (± 8.41)			
MCHC,Week 4,n=31,31,19,20,25	2.4 (± 9.32)			
MCHC,Week 8,n=28,24,18,20,20	6.7 (± 8.19)			
MCHC,Week 12,n=25,23,18,20,20	4.9 (± 7.81)			
MCHC,Week 16,n=22,21,17,17,17	4.5 (± 9.62)			
MCHC,Week 20,n=19,18,14,16,14	4.6 (± 12.48)			
MCHC,Week 24,n=16,16,13,15,14	4.9 (± 11.49)			
MCHC,Week 28,n=13,14,10,12,11	-0.4 (± 7.86)			
MCHC,Week 32,n=13,11,8,10,11	1.4 (± 8.58)			
MCHC,Week 36,n=10,10,8,10,10	4.2 (± 5.90)			
MCHC,Week 40,n=10,9,7,8,9	13.9 (± 12.39)			
MCHC,Week 44,n=8,8,4,5,8	12.1 (± 10.99)			
MCHC,Week 48,n=6,7,2,6,4	9.3 (± 9.32)			
MCHC,Week 52,n=6,4,3,4,3	5.0 (± 9.85)			
Hemoglobin,Week 2,n=38,39,24,24,25	-0.9 (± 5.44)			
Hemoglobin,Week 4,n=36,37,24,22,27	-2.1 (± 6.86)			
Hemoglobin,Week 8,n=34,29,23,22,21	-2.8 (± 7.41)			
Hemoglobin,Week 12,n=31,28,23,22,22	-1.4 (± 7.10)			
Hemoglobin,Week 16,n=27,26,21,19,19	-1.7 (± 7.47)			
Hemoglobin,Week 20,n=25,23,18,18,16	-0.6 (± 6.22)			
Hemoglobin,Week 24,n=22,21,16,16,16	-0.9 (± 6.43)			
Hemoglobin,Week 28,n=18,18,12,14,13	-1.5 (± 8.88)			
Hemoglobin,Week 32,n=19,15,10,12,13	0.8 (± 9.64)			
Hemoglobin,Week 36,n=15,12,10,12,12	1.3 (± 9.68)			
Hemoglobin,Week 40,n=14,11,8,10,10	-0.4 (± 7.86)			
Hemoglobin,Week 44,n=11,10,6,8,9	2.8 (± 12.85)			
Hemoglobin,Week 48,n=9,8,4,8,5	7.6 (± 15.57)			
Hemoglobin,Week 52,n=8,5,5,5,4	2.8 (± 13.57)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in hematology parameter-Hematocrit

End point title	Part A: Change from Baseline in hematology parameter-Hematocrit
End point description:	
Blood samples were collected to analyze the hematology parameter Hematocrit. Change from Baseline is presented for this parameter. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.	
End point type	Secondary
End point timeframe:	
Baseline (Week 0) and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52	

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Week 2,n=38,39,24,24,25	0.0040 (± 0.01988)	0.0060 (± 0.02186)	0.0008 (± 0.02909)	-0.0063 (± 0.02491)
Week 4,n=36,37,24,22,27	0.0059 (± 0.01903)	0.0048 (± 0.02635)	0.0040 (± 0.01531)	-0.0035 (± 0.02676)
Week 8,n=34,29,23,22,21	0.0101 (± 0.02601)	0.0054 (± 0.03213)	0.0019 (± 0.02110)	-0.0054 (± 0.03286)
Week 12,n=31,28,23,22,22	0.0087 (± 0.02386)	0.0148 (± 0.03272)	0.0059 (± 0.01970)	-0.0118 (± 0.03281)
Week 16,n=27,26,21,19,19	-0.0037 (± 0.02187)	0.0049 (± 0.02833)	0.0008 (± 0.01961)	-0.0135 (± 0.02976)
Week 20,n=25,23,18,18,16	-0.0063 (± 0.02436)	0.0066 (± 0.03019)	-0.0015 (± 0.01398)	-0.0184 (± 0.02972)
Week 24,n=22,21,16,16,16	-0.0017 (± 0.02882)	0.0010 (± 0.02839)	0.0089 (± 0.01973)	-0.0133 (± 0.03478)
Week 28,n=18,18,12,14,13	-0.0089 (± 0.02917)	0.0039 (± 0.03455)	-0.0046 (± 0.01858)	-0.0186 (± 0.02814)
Week 32,n=19,15,10,12,13	-0.0076 (± 0.02782)	0.0027 (± 0.02994)	-0.0060 (± 0.03161)	-0.0176 (± 0.02473)
Week 36,n=15,12,10,12,12	0.0012 (± 0.02603)	0.0036 (± 0.03232)	-0.0054 (± 0.01811)	-0.0198 (± 0.02570)
Week 40,n=14,11,8,10,10	-0.0115 (± 0.03075)	-0.0052 (± 0.03398)	-0.0009 (± 0.01086)	-0.0193 (± 0.02157)
Week 44,n=11,10,6,7,9	-0.0185 (± 0.03039)	0.0054 (± 0.03463)	-0.0097 (± 0.02548)	-0.0126 (± 0.03225)
Week 48,n=9,8,4,8,5	-0.0136 (± 0.02709)	-0.0025 (± 0.03217)	-0.0053 (± 0.04366)	-0.0216 (± 0.03428)
Week 52,n=8,5,5,5,4	-0.0135 (± 0.02112)	0.0016 (± 0.04082)	0.0058 (± 0.04370)	-0.0006 (± 0.01558)

End point values	PartA:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Week 2,n=38,39,24,24,25	-0.0030 (± 0.01813)			
Week 4,n=36,37,24,22,27	-0.0087 (± 0.02004)			
Week 8,n=34,29,23,22,21	-0.0159 (± 0.01918)			
Week 12,n=31,28,23,22,22	-0.0095 (± 0.02108)			
Week 16,n=27,26,21,19,19	-0.0095 (± 0.02347)			
Week 20,n=25,23,18,18,16	-0.0062 (± 0.02076)			
Week 24,n=22,21,16,16,16	-0.0077 (± 0.01599)			
Week 28,n=18,18,12,14,13	-0.0035 (± 0.02785)			
Week 32,n=19,15,10,12,13	0.0025 (± 0.02741)			
Week 36,n=15,12,10,12,12	0.0018 (± 0.03090)			
Week 40,n=14,11,8,10,10	-0.0160 (± 0.02099)			
Week 44,n=11,10,6,7,9	-0.0037 (± 0.03048)			
Week 48,n=9,8,4,8,5	0.0144 (± 0.04123)			
Week 52,n=8,5,5,5,4	0.0025 (± 0.03288)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in hematology parameter -Erythrocytes Mean Corpuscular Volume

End point title	Part A: Change from Baseline in hematology parameter - Erythrocytes Mean Corpuscular Volume
End point description: Blood samples were collected to analyze the hematology parameter Erythrocytes Mean Corpuscular Volume. Change from Baseline is presented for this parameter. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.	
End point type	Secondary
End point timeframe: Baseline (Week 0) and Weeks 2, 4 ,8,12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52	

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Femtoliter				
arithmetic mean (standard deviation)				
Week 2,n=38,39,24,24,25	0.5 (± 1.35)	0.5 (± 1.64)	0.5 (± 1.38)	0.6 (± 1.38)
Week 4,n=36,37,24,22,27	0.9 (± 1.95)	1.1 (± 2.15)	1.0 (± 1.69)	0.6 (± 1.68)
Week 8,n=34,29,23,22,21	1.2 (± 2.54)	1.8 (± 3.27)	1.9 (± 2.72)	1.7 (± 2.34)
Week 12,n=31,28,23,22,22	0.8 (± 3.41)	2.0 (± 4.29)	2.6 (± 3.14)	0.9 (± 3.16)
Week 16,n=27,26,21,19,19	1.0 (± 4.14)	2.2 (± 4.36)	3.1 (± 3.37)	0.4 (± 4.03)
Week 20,n=25,23,18,18,16	1.2 (± 4.42)	1.8 (± 4.35)	2.1 (± 3.12)	-0.5 (± 4.72)
Week 24,n=22,21,16,16,16	1.1 (± 4.20)	1.1 (± 3.91)	2.6 (± 3.36)	-1.0 (± 4.44)
Week 28,n=18,18,12,14,13	0.6 (± 4.02)	1.4 (± 4.19)	2.0 (± 2.26)	-0.4 (± 4.43)
Week 32,n=19,15,10,12,13	0.9 (± 4.42)	2.0 (± 4.44)	1.3 (± 3.13)	0.3 (± 4.89)
Week 36,n=15,12,10,12,12	1.8 (± 3.49)	1.6 (± 4.76)	0.9 (± 2.47)	-0.5 (± 4.93)
Week 40,n=14,11,8,10,10	0.6 (± 3.73)	1.8 (± 5.25)	2.0 (± 2.83)	0.4 (± 4.95)
Week 44,n=11,10,6,8,9	-0.5 (± 3.50)	2.5 (± 5.08)	1.7 (± 3.50)	-0.7 (± 6.87)
Week 48,n=9,8,4,8,5	-0.4 (± 3.50)	3.3 (± 4.95)	2.3 (± 4.50)	-1.1 (± 6.92)
Week 52,n=8,5,5,5,4	-0.6 (± 3.02)	3.2 (± 5.12)	1.4 (± 4.16)	3.2 (± 5.72)

End point values	PartA:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Femtoliter				
arithmetic mean (standard deviation)				
Week 2,n=38,39,24,24,25	0.4 (± 1.44)			
Week 4,n=36,37,24,22,27	0.6 (± 2.28)			
Week 8,n=34,29,23,22,21	-0.2 (± 2.91)			
Week 12,n=31,28,23,22,22	0.3 (± 4.07)			
Week 16,n=27,26,21,19,19	-0.3 (± 4.98)			
Week 20,n=25,23,18,18,16	0.1 (± 3.54)			
Week 24,n=22,21,16,16,16	-1.6 (± 4.84)			
Week 28,n=18,18,12,14,13	-0.5 (± 3.95)			
Week 32,n=19,15,10,12,13	-0.5 (± 3.64)			
Week 36,n=15,12,10,12,12	-0.2 (± 2.55)			
Week 40,n=14,11,8,10,10	-2.1 (± 3.00)			
Week 44,n=11,10,6,8,9	-0.7 (± 2.83)			
Week 48,n=9,8,4,8,5	2.0 (± 2.12)			
Week 52,n=8,5,5,5,4	1.0 (± 2.58)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A:Change from Baseline in hematology parameter-Erythrocytes Mean Corpuscular Hemoglobin

End point title	Part A:Change from Baseline in hematology parameter-Erythrocytes Mean Corpuscular Hemoglobin
End point description: Blood samples were collected to analyze the hematology parameter Erythrocytes Mean Corpuscular Hemoglobin. Change from Baseline is presented for this parameter. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.	
End point type	Secondary
End point timeframe: Baseline (Week 0) and Weeks 2, 4 ,8,12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52	

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Picograms				
arithmetic mean (standard deviation)				
Week 2,n=38,39,24,24,25	0.13 (± 0.571)	0.29 (± 0.730)	0.42 (± 0.512)	0.12 (± 0.494)
Week 4,n=36,37,24,22,27	0.53 (± 0.786)	0.58 (± 0.877)	0.55 (± 0.672)	0.25 (± 0.458)
Week 8,n=34,29,23,22,21	0.96 (± 1.041)	1.20 (± 1.056)	1.16 (± 1.178)	0.60 (± 0.751)
Week 12,n=31,28,23,22,22	0.94 (± 1.341)	1.43 (± 1.372)	1.38 (± 1.630)	0.44 (± 1.110)
Week 16,n=27,26,21,19,19	1.16 (± 1.345)	1.59 (± 1.617)	1.83 (± 1.424)	0.24 (± 1.508)
Week 20,n=25,23,18,18,16	1.24 (± 1.529)	1.69 (± 1.605)	1.48 (± 1.256)	0.14 (± 1.666)
Week 24,n=22,21,16,16,16	0.97 (± 1.491)	1.80 (± 1.663)	1.34 (± 1.230)	-0.04 (± 1.727)
Week 28,n=18,18,12,14,13	0.91 (± 1.659)	1.48 (± 1.618)	1.47 (± 1.409)	0.21 (± 2.000)
Week 32,n=19,15,10,12,13	1.01 (± 1.498)	1.57 (± 1.694)	1.27 (± 1.111)	0.68 (± 2.103)
Week 36,n=15,12,10,12,12	1.42 (± 0.944)	1.29 (± 1.905)	1.39 (± 1.005)	0.68 (± 2.327)
Week 40,n=14,11,8,10,10	1.30 (± 0.818)	1.75 (± 1.914)	1.91 (± 1.373)	0.71 (± 2.617)
Week 44,n=11,10,6,8,9	1.16 (± 0.727)	1.83 (± 2.214)	1.63 (± 1.178)	0.30 (± 2.460)
Week 48,n=9,8,4,8,5	1.36 (± 0.633)	2.25 (± 2.194)	1.73 (± 1.389)	0.14 (± 2.934)
Week 52,n=8,5,5,5,4	1.44 (± 0.950)	2.70 (± 1.744)	2.24 (± 1.484)	1.84 (± 1.889)

End point values	PartA:Placebo			
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	SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Picograms				
arithmetic mean (standard deviation)				
Week 2,n=38,39,24,24,25	0.22 (± 0.678)			
Week 4,n=36,37,24,22,27	0.36 (± 0.892)			
Week 8,n=34,29,23,22,21	0.49 (± 1.022)			
Week 12,n=31,28,23,22,22	0.47 (± 1.480)			
Week 16,n=27,26,21,19,19	0.22 (± 1.927)			
Week 20,n=25,23,18,18,16	0.39 (± 1.696)			
Week 24,n=22,21,16,16,16	-0.08 (± 2.041)			
Week 28,n=18,18,12,14,13	-0.20 (± 1.493)			
Week 32,n=19,15,10,12,13	-0.14 (± 1.413)			
Week 36,n=15,12,10,12,12	0.15 (± 0.971)			
Week 40,n=14,11,8,10,10	0.44 (± 1.492)			
Week 44,n=11,10,6,8,9	0.77 (± 1.261)			
Week 48,n=9,8,4,8,5	1.32 (± 1.119)			
Week 52,n=8,5,5,5,4	0.80 (± 1.068)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A:Change from Baseline in hematology parameter- Erythrocytes

End point title	Part A:Change from Baseline in hematology parameter- Erythrocytes
End point description:	
Blood samples were collected to analyze the hematology parameter Erythrocytes. Change from Baseline is presented for this parameter. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.	
End point type	Secondary
End point timeframe:	
Baseline (Week 0) and Weeks 2, 4 ,8,12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52	

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: trillion cells per liter				
arithmetic mean (standard deviation)				
Week 2,n=38,39,24,24,25	0.01 (± 0.232)	0.02 (± 0.265)	-0.01 (± 0.303)	-0.10 (± 0.254)

Week 4,n=36,37,24,22,27	0.01 (± 0.208)	-0.01 (± 0.311)	-0.01 (± 0.202)	-0.09 (± 0.268)
Week 8,n=34,29,23,22,21	0.04 (± 0.249)	-0.04 (± 0.406)	-0.08 (± 0.300)	-0.16 (± 0.372)
Week 12,n=31,28,23,22,22	0.03 (± 0.255)	0.05 (± 0.417)	-0.07 (± 0.265)	-0.20 (± 0.379)
Week 16,n=27,26,21,19,19	-0.09 (± 0.238)	-0.07 (± 0.312)	-0.14 (± 0.282)	-0.19 (± 0.399)
Week 20,n=25,23,18,18,16	-0.13 (± 0.263)	-0.03 (± 0.305)	-0.12 (± 0.183)	-0.20 (± 0.461)
Week 24,n=22,21,16,16,16	-0.09 (± 0.270)	-0.06 (± 0.282)	-0.04 (± 0.234)	-0.11 (± 0.464)
Week 28,n=18,18,12,14,13	-0.14 (± 0.295)	-0.04 (± 0.327)	-0.16 (± 0.231)	-0.18 (± 0.377)
Week 32,n=19,15,10,12,13	-0.13 (± 0.292)	-0.09 (± 0.259)	-0.13 (± 0.330)	-0.22 (± 0.321)
Week 36,n=15,12,10,12,12	-0.08 (± 0.262)	-0.04 (± 0.378)	-0.10 (± 0.183)	-0.21 (± 0.358)
Week 40,n=14,11,8,10,10	-0.16 (± 0.234)	-0.16 (± 0.380)	-0.09 (± 0.189)	-0.22 (± 0.301)
Week 44,n=11,10,6,7,9	-0.18 (± 0.286)	-0.10 (± 0.333)	-0.17 (± 0.320)	-0.10 (± 0.216)
Week 48,n=9,8,4,8,5	-0.14 (± 0.240)	-0.23 (± 0.266)	-0.18 (± 0.457)	-0.20 (± 0.251)
Week 52,n=8,5,5,5,4	-0.16 (± 0.283)	-0.18 (± 0.370)	-0.02 (± 0.531)	-0.18 (± 0.192)

End point values	PartA:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: trillion cells per liter				
arithmetic mean (standard deviation)				
Week 2,n=38,39,24,24,25	-0.07 (± 0.221)			
Week 4,n=36,37,24,22,27	-0.14 (± 0.248)			
Week 8,n=34,29,23,22,21	-0.17 (± 0.219)			
Week 12,n=31,28,23,22,22	-0.11 (± 0.237)			
Week 16,n=27,26,21,19,19	-0.11 (± 0.303)			
Week 20,n=25,23,18,18,16	-0.08 (± 0.286)			
Week 24,n=22,21,16,16,16	-0.01 (± 0.289)			
Week 28,n=18,18,12,14,13	-0.02 (± 0.387)			
Week 32,n=19,15,10,12,13	0.04 (± 0.362)			
Week 36,n=15,12,10,12,12	0.03 (± 0.391)			
Week 40,n=14,11,8,10,10	-0.10 (± 0.330)			
Week 44,n=11,10,6,7,9	-0.03 (± 0.367)			
Week 48,n=9,8,4,8,5	0.04 (± 0.434)			

Week 52,n=8,5,5,5,4	-0.05 (± 0.332)			
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Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in clinical chemistry parameters- Calcium, Carbon Dioxide, Chloride, Glucose, Phosphate, Potassium, Sodium and Urea

End point title	Part A: Change from Baseline in clinical chemistry parameters- Calcium, Carbon Dioxide, Chloride, Glucose, Phosphate, Potassium, Sodium and Urea
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End point description:

Blood samples were collected to analyze the chemistry parameters including Calcium, Carbon Dioxide, Chloride, Glucose, Phosphate, Potassium, Sodium and Urea . Change from Baseline is presented for these parameters. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4 ,8,12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
calcium,Week 2,n=38,39,26,24,26	0.002 (± 0.1056)	0.006 (± 0.0853)	-0.008 (± 0.0817)	0.008 (± 0.1050)
calcium,Week 4,n=37,38,25,23,27	0.009 (± 0.0974)	0.008 (± 0.0968)	0.013 (± 0.0649)	-0.016 (± 0.0922)
calcium,Week 8,n=34,31,24,22,23	0.032 (± 0.1114)	0.049 (± 0.0879)	0.005 (± 0.0764)	0.020 (± 0.0918)
calcium,Week 12,n=32,28,24,22,21	0.019 (± 0.1200)	0.072 (± 0.0789)	-0.001 (± 0.0750)	0.011 (± 0.0913)
calcium,Week 16,n=28,26,22,19,18	0.009 (± 0.0974)	0.050 (± 0.0808)	0.018 (± 0.0954)	-0.008 (± 0.0707)
calcium,Week 20,n=25,23,19,18,16	0.018 (± 0.1080)	0.070 (± 0.0987)	0.032 (± 0.0933)	0.000 (± 0.0884)
calcium,Week 24,n=22,21,16,17,16	0.008 (± 0.1029)	0.064 (± 0.0927)	0.032 (± 0.1077)	-0.002 (± 0.0748)
calcium,Week 28,n=19,18,12,13,14	0.006 (± 0.1102)	0.066 (± 0.1106)	0.054 (± 0.1232)	0.018 (± 0.0838)
calcium,Week 32,n=19,15,10,12,13	0.029 (± 0.1119)	0.044 (± 0.0923)	0.059 (± 0.0737)	-0.008 (± 0.0978)
calcium,Week 36,n=15,12,10,12,13	0.016 (± 0.0789)	0.055 (± 0.0773)	0.075 (± 0.0738)	-0.038 (± 0.1025)
calcium,Week 40,n=15,11,9,10,10	0.077 (± 0.1012)	0.016 (± 0.0662)	0.008 (± 0.0930)	-0.042 (± 0.0561)

calcium,Week 44,n=11,11,6,8,9	0.042 (± 0.1480)	0.025 (± 0.0908)	-0.002 (± 0.0475)	-0.035 (± 0.1638)
calcium,Week 48,n=9,8,5,8,5	-0.007 (± 0.1126)	0.028 (± 0.0956)	-0.018 (± 0.0769)	-0.035 (± 0.0769)
calcium,Week 52,n=9,5,5,5,4	0.013 (± 0.0907)	0.076 (± 0.1108)	0.026 (± 0.0747)	-0.056 (± 0.1161)
Carbon Dioxide,Week 2,n=38,39,26,24,26	0.7 (± 2.42)	0.6 (± 2.55)	0.5 (± 2.53)	-0.3 (± 2.31)
Carbon Dioxide,Week 4,n=37,38,25,23,27	0.1 (± 2.03)	0.2 (± 2.68)	0.4 (± 2.69)	0.2 (± 1.75)
Carbon Dioxide,Week 8,n=34,31,24,22,23	0.1 (± 3.39)	0.3 (± 2.89)	0.0 (± 2.69)	0.0 (± 2.01)
Carbon Dioxide,Week 12,n=32,28,24,22,21	0.1 (± 2.66)	0.6 (± 2.53)	-0.4 (± 2.28)	0.0 (± 1.94)
Carbon Dioxide,Week 16,n=28,26,22,19,18	0.1 (± 2.97)	0.5 (± 2.47)	0.8 (± 2.94)	-0.1 (± 1.88)
Carbon Dioxide,Week 20,n=25,23,19,18,16	0.1 (± 2.98)	-0.1 (± 3.17)	-0.1 (± 2.70)	-0.3 (± 2.83)
Carbon Dioxide,Week 24,n=22,21,16,17,16	0.4 (± 3.10)	0.4 (± 3.11)	-0.8 (± 2.65)	0.5 (± 2.29)
Carbon Dioxide,Week 28,n=19,18,12,13,14	-1.6 (± 2.83)	0.4 (± 3.63)	-1.0 (± 2.04)	-0.4 (± 2.36)
Carbon Dioxide,Week 32,n=19,15,10,12,13	-1.0 (± 3.65)	0.8 (± 2.08)	-1.4 (± 2.17)	-0.6 (± 2.43)
Carbon Dioxide,Week 36,n=15,12,10,12,13	-1.1 (± 2.28)	0.3 (± 3.72)	-0.9 (± 1.97)	-0.3 (± 3.63)
Carbon Dioxide,Week 40,n=15,11,6,10,10	-1.5 (± 3.16)	0.9 (± 3.75)	-1.7 (± 2.35)	-0.8 (± 2.70)
Carbon Dioxide,Week 44,n=11,11,6,8,9	-1.7 (± 2.72)	1.6 (± 3.50)	0.0 (± 3.03)	-1.6 (± 1.60)
Carbon Dioxide,Week 48,n=9,8,5,8,5	-2.6 (± 2.70)	0.5 (± 3.59)	-1.0 (± 2.65)	0.0 (± 1.77)
Carbon Dioxide,Week 52,n=9,5,5,5,4	-1.1 (± 1.76)	1.2 (± 2.68)	-1.2 (± 1.48)	-0.4 (± 1.34)
Chloride,Week 2,n=38,39,26,24,26	1.1 (± 2.36)	0.6 (± 1.79)	0.7 (± 1.76)	1.0 (± 2.16)
Chloride,Week 4,n=37,38,25,23,27	1.8 (± 2.34)	1.6 (± 2.10)	1.4 (± 1.87)	0.7 (± 2.14)
Chloride,Week 8,n=34,31,24,22,23	2.5 (± 2.12)	2.4 (± 2.06)	2.0 (± 2.65)	1.0 (± 2.18)
Chloride,Week 12,n=32,28,24,22,21	2.9 (± 2.54)	1.8 (± 3.03)	2.4 (± 2.30)	0.6 (± 2.06)
Chloride,Week 16,n=28,26,22,19,18	3.0 (± 2.27)	2.3 (± 2.54)	2.2 (± 2.46)	1.1 (± 2.04)
Chloride,Week 20,n=25,23,19,18,16	3.3 (± 2.88)	2.0 (± 2.11)	2.1 (± 2.49)	1.3 (± 2.22)
Chloride,Week 24,n=22,21,16,17,16	3.4 (± 3.42)	2.7 (± 2.51)	1.6 (± 3.16)	1.0 (± 2.12)
Chloride,Week 28,n=19,18,12,13,14	3.9 (± 3.13)	2.8 (± 2.80)	2.8 (± 2.49)	0.2 (± 3.49)
Chloride,Week 32,n=19,15,10,12,13	3.4 (± 2.73)	1.9 (± 2.59)	2.0 (± 2.26)	-0.1 (± 4.17)
Chloride,Week 36,n=15,12,10,12,13	3.8 (± 1.74)	2.4 (± 2.78)	1.9 (± 2.47)	1.1 (± 1.88)
Chloride,Week 40,n=15,11,9,10,10	3.3 (± 2.49)	3.6 (± 1.12)	1.4 (± 1.94)	1.9 (± 1.45)
Chloride,Week 44,n=11,11,6,8,9	3.8 (± 2.23)	3.4 (± 1.91)	0.2 (± 2.14)	1.1 (± 2.03)
Chloride,Week 48,n=9,8,5,8,5	4.6 (± 1.88)	2.1 (± 2.23)	2.0 (± 1.58)	1.8 (± 1.58)
Chloride,Week 52,n=9,5,5,5,4	4.8 (± 1.09)	2.2 (± 1.64)	0.2 (± 3.83)	3.6 (± 1.95)
Glucose,Week 2,n=38,39,26,24,26	-0.03 (± 2.568)	-0.46 (± 1.671)	0.01 (± 1.237)	0.29 (± 1.358)
Glucose,Week 4,n=37,38,25,23,27	-0.10 (± 2.676)	-0.35 (± 1.929)	0.38 (± 1.601)	0.31 (± 1.466)
Glucose,Week 8,n=34,31,24,22,23	-0.29 (± 2.507)	-0.58 (± 2.606)	-0.12 (± 1.265)	0.10 (± 1.579)
Glucose,Week 12,n=32,28,24,22,21	-0.64 (± 2.219)	-0.63 (± 2.134)	-0.33 (± 1.163)	-0.25 (± 1.164)
Glucose,Week 16,n=28,26,22,19,18	-0.71 (± 2.485)	0.33 (± 1.941)	-0.29 (± 1.113)	-0.12 (± 1.414)
Glucose,Week 20,n=25,23,19,18,16	-0.66 (± 2.701)	-0.46 (± 1.550)	0.46 (± 1.714)	-0.33 (± 1.435)
Glucose,Week 24,n=22,21,16,17,16	-0.72 (± 2.701)	-0.44 (± 1.632)	-0.23 (± 1.217)	-0.38 (± 1.290)

Glucose,Week 28,n=19,18,12,13,14	-0.91 (± 2.990)	-0.32 (± 1.510)	0.58 (± 1.627)	-0.25 (± 1.278)
Glucose,Week 32,n=19,15,10,12,13	-0.74 (± 3.492)	-0.48 (± 1.533)	0.72 (± 1.795)	-0.05 (± 1.363)
Glucose,Week 36,n=15,12,10,12,13	-1.14 (± 3.268)	-0.35 (± 1.861)	0.05 (± 1.019)	-0.50 (± 1.261)
Glucose,Week 40,n=15,11,9,10,10	-0.99 (± 3.465)	-0.33 (± 2.376)	0.22 (± 1.203)	-0.22 (± 1.192)
Glucose,Week 44,n=11,11,6,8,9	-1.39 (± 3.789)	-0.05 (± 1.954)	-0.27 (± 0.940)	0.30 (± 0.739)
Glucose,Week 48,n=9,8,5,8,5	-1.39 (± 4.249)	-0.93 (± 2.077)	-0.62 (± 1.441)	-0.88 (± 1.369)
Glucose,Week 52,n=9,5,5,5,4	-1.51 (± 4.466)	-0.94 (± 2.707)	-0.26 (± 1.316)	-0.72 (± 1.308)
Phosphate,Week 2,n=38,39,26,24,26	0.056 (± 0.2249)	-0.004 (± 0.1930)	0.017 (± 0.1886)	-0.025 (± 0.1622)
Phosphate,Week 4,n=37,38,25,23,27	0.071 (± 0.1944)	-0.011 (± 0.2501)	0.093 (± 0.1848)	0.006 (± 0.1883)
Phosphate,Week 8,n=34,31,24,22,23	0.088 (± 0.1786)	0.091 (± 0.2098)	0.112 (± 0.1588)	0.045 (± 0.1971)
Phosphate,Week 12,n=32,28,24,22,21	0.122 (± 0.2404)	0.154 (± 0.2377)	0.190 (± 0.1725)	0.067 (± 0.1873)
Phosphate,Week 16,n=28,26,22,19,18	0.113 (± 0.1976)	0.139 (± 0.2315)	0.146 (± 0.1612)	0.025 (± 0.1589)
Phosphate,Week 20,n=25,23,19,18,16	0.070 (± 0.1860)	0.160 (± 0.2436)	0.141 (± 0.2257)	0.043 (± 0.1854)
Phosphate,Week 24,n=22,21,16,17,16	0.132 (± 0.2066)	0.163 (± 0.2383)	0.181 (± 0.1778)	0.055 (± 0.1728)
Phosphate,Week 28,n=19,18,12,13,14	0.156 (± 0.1873)	0.090 (± 0.2543)	0.191 (± 0.1980)	0.073 (± 0.2017)
Phosphate,Week 32,n=19,15,10,12,13	0.164 (± 0.1166)	0.101 (± 0.2160)	0.214 (± 0.2086)	0.048 (± 0.1677)
Phosphate,Week 36,n=15,12,10,12,13	0.111 (± 0.1786)	0.068 (± 0.2204)	0.304 (± 0.2112)	0.098 (± 0.1939)
Phosphate,Week 40,n=15,11,6,10,10	0.221 (± 0.1902)	-0.007 (± 0.2007)	0.104 (± 0.1948)	0.073 (± 0.1849)
Phosphate,Week 44,n=11,11,6,8,9	0.142 (± 0.2117)	0.025 (± 0.1874)	0.090 (± 0.2131)	-0.065 (± 0.2267)
Phosphate,Week 48,n=9,8,5,8,5	0.029 (± 0.2136)	-0.054 (± 0.2203)	0.028 (± 0.2611)	-0.015 (± 0.1561)
Phosphate,Week 52,n=9,5,5,5,4	0.049 (± 0.2235)	-0.036 (± 0.2779)	0.208 (± 0.1583)	0.036 (± 0.0865)
Potassium,Week 2,n=38,39,26,24,26	0.03 (± 0.372)	-0.03 (± 0.437)	-0.02 (± 0.401)	0.18 (± 0.336)
Potassium,Week 4,n=37,38,25,23,27	-0.13 (± 0.319)	-0.04 (± 0.412)	-0.10 (± 0.453)	0.06 (± 0.329)
Potassium,Week 8,n=34,31,24,22,23	0.01 (± 0.364)	0.05 (± 0.437)	-0.11 (± 0.422)	0.10 (± 0.333)
Potassium,Week 12,n=32,28,24,22,21	-0.12 (± 0.333)	0.15 (± 0.810)	-0.10 (± 0.346)	0.06 (± 0.336)
Potassium,Week 16,n=28,26,22,19,18	0.01 (± 0.376)	0.03 (± 0.439)	-0.02 (± 0.358)	0.15 (± 0.345)
Potassium,Week 20,n=25,23,19,18,16	0.04 (± 0.394)	0.07 (± 0.556)	0.02 (± 0.417)	0.10 (± 0.287)
Potassium,Week 24,n=22,21,16,17,16	0.05 (± 0.447)	-0.01 (± 0.403)	-0.13 (± 0.368)	0.15 (± 0.371)
Potassium,Week 28,n=19,18,12,13,14	0.12 (± 0.288)	0.07 (± 0.470)	0.17 (± 0.414)	0.08 (± 0.297)
Potassium,Week 32,n=19,15,10,12,13	0.16 (± 0.437)	0.01 (± 0.448)	0.17 (± 0.333)	0.19 (± 0.365)
Potassium,Week 36,n=15,12,10,12,13	0.16 (± 0.429)	-0.07 (± 0.475)	0.18 (± 0.408)	0.18 (± 0.341)
Potassium,Week 40,n=15,11,9,10,10	0.24 (± 0.534)	-0.03 (± 0.476)	0.01 (± 0.276)	0.03 (± 0.450)

Potassium, Week 44, n=11, 11, 6, 8, 9	0.16 (± 0.287)	-0.13 (± 0.478)	-0.13 (± 0.288)	0.15 (± 0.385)
Potassium, Week 48, n=9, 8, 5, 8, 5	0.21 (± 0.352)	0.06 (± 0.644)	-0.04 (± 0.182)	0.16 (± 0.283)
Potassium, Week 52, n=9, 5, 5, 5, 4	0.22 (± 0.186)	-0.16 (± 0.434)	-0.10 (± 0.418)	0.06 (± 0.445)
Sodium, Week 2, n=38, 39, 26, 24, 26	0.3 (± 2.11)	0.0 (± 2.33)	-0.8 (± 2.37)	-0.2 (± 1.52)
Sodium, Week 4, n=37, 38, 25, 23, 27	0.7 (± 2.15)	0.4 (± 2.11)	0.2 (± 2.29)	0.0 (± 1.43)
Sodium, Week 8, n=34, 31, 24, 22, 23	1.1 (± 2.10)	0.9 (± 3.12)	0.1 (± 2.32)	0.5 (± 1.50)
Sodium, Week 12, n=32, 28, 24, 22, 21	1.8 (± 2.46)	0.5 (± 3.90)	0.6 (± 1.76)	0.5 (± 1.79)
Sodium, Week 16, n=28, 26, 22, 19, 18	1.0 (± 2.28)	0.6 (± 3.09)	-0.2 (± 2.25)	-0.3 (± 1.37)
Sodium, Week 20, n=25, 23, 19, 18, 16	1.0 (± 2.23)	0.6 (± 2.79)	-0.3 (± 2.60)	-0.6 (± 0.92)
Sodium, Week 24, n=22, 21, 16, 17, 16	0.9 (± 2.31)	1.0 (± 1.83)	-0.4 (± 2.00)	0.4 (± 1.50)
Sodium, Week 28, n=19, 18, 12, 13, 14	0.9 (± 2.27)	1.2 (± 2.75)	0.5 (± 1.93)	-0.8 (± 3.22)
Sodium, Week 32, n=19, 15, 10, 12, 13	0.7 (± 2.31)	-0.3 (± 2.63)	-0.2 (± 2.04)	-0.8 (± 3.16)
Sodium, Week 36, n=15, 12, 10, 12, 13	0.5 (± 1.96)	0.6 (± 2.43)	-0.4 (± 2.07)	-0.2 (± 1.85)
Sodium, Week 40, n=15, 11, 9, 10, 10	0.1 (± 2.17)	1.2 (± 2.23)	-1.2 (± 2.49)	0.5 (± 1.58)
Sodium, Week 44, n=11, 11, 6, 8, 9	0.5 (± 1.97)	0.4 (± 2.58)	-2.0 (± 2.53)	-0.8 (± 1.28)
Sodium, Week 48, n=9, 8, 5, 8, 5	-0.3 (± 1.87)	0.8 (± 2.76)	-0.6 (± 2.07)	0.3 (± 1.91)
Sodium, Week 52, n=9, 5, 5, 5, 4	0.7 (± 1.66)	0.4 (± 2.51)	-0.8 (± 3.11)	1.6 (± 1.14)
Urea, Week 2, n=38, 39, 26, 24, 26	0.05 (± 1.210)	-0.16 (± 1.776)	0.28 (± 1.439)	-0.31 (± 1.458)
Urea, Week 4, n=37, 38, 25, 23, 27	-0.09 (± 1.592)	-0.61 (± 1.514)	-0.06 (± 1.277)	-0.22 (± 1.022)
Urea, Week 8, n=34, 31, 24, 22, 23	-0.36 (± 1.938)	-0.99 (± 1.826)	-0.40 (± 1.574)	-0.91 (± 0.970)
Urea, Week 12, n=32, 28, 24, 22, 21	-0.65 (± 1.617)	-1.20 (± 1.778)	-0.62 (± 1.501)	-1.12 (± 1.457)
Urea, Week 16, n=28, 26, 22, 19, 18	-0.56 (± 2.009)	-0.52 (± 1.612)	-0.72 (± 1.232)	-0.40 (± 1.580)
Urea, Week 20, n=25, 23, 19, 18, 16	-0.30 (± 1.675)	-0.70 (± 1.379)	-0.70 (± 1.197)	-0.31 (± 1.470)
Urea, Week 24, n=22, 21, 16, 17, 16	-0.48 (± 1.901)	-0.22 (± 2.044)	-0.80 (± 1.717)	-0.65 (± 1.457)
Urea, Week 28, n=19, 18, 12, 13, 14	-0.45 (± 1.745)	-0.42 (± 1.510)	-0.73 (± 1.317)	0.23 (± 1.111)
Urea, Week 32, n=19, 15, 10, 12, 13	-0.16 (± 2.086)	-0.64 (± 1.479)	-0.83 (± 1.382)	-0.76 (± 1.071)
Urea, Week 36, n=15, 12, 10, 12, 13	0.06 (± 1.967)	-1.43 (± 1.828)	-0.93 (± 1.113)	-0.01 (± 0.973)
Urea, Week 40, n=15, 11, 9, 10, 10	-0.17 (± 1.775)	-0.78 (± 0.603)	-0.98 (± 1.237)	-0.76 (± 1.552)
Urea, Week 44, n=11, 11, 6, 8, 9	-0.46 (± 3.119)	-1.05 (± 1.234)	-0.63 (± 1.359)	-0.76 (± 1.274)
Urea, Week 48, n=9, 8, 5, 8, 5	-0.18 (± 3.535)	-1.58 (± 1.450)	-0.06 (± 1.311)	-0.51 (± 1.225)
Urea, Week 52, n=9, 5, 5, 5, 4	-0.26 (± 2.508)	-1.22 (± 1.671)	-0.76 (± 1.647)	-0.82 (± 0.782)

End point values	PartA: Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Millimoles per liter				

arithmetic mean (standard deviation)				
calcium,Week 2,n=38,39,26,24,26	0.013 (± 0.0812)			
calcium,Week 4,n=37,38,25,23,27	-0.001 (± 0.0899)			
calcium,Week 8,n=34,31,24,22,23	0.013 (± 0.0615)			
calcium,Week 12,n=32,28,24,22,21	0.016 (± 0.0851)			
calcium,Week 16,n=28,26,22,19,18	0.044 (± 0.0768)			
calcium,Week 20,n=25,23,19,18,16	0.012 (± 0.0932)			
calcium,Week 24,n=22,21,16,17,16	0.009 (± 0.0702)			
calcium,Week 28,n=19,18,12,13,14	0.076 (± 0.1108)			
calcium,Week 32,n=19,15,10,12,13	0.075 (± 0.1271)			
calcium,Week 36,n=15,12,10,12,13	0.053 (± 0.0957)			
calcium,Week 40,n=15,11,9,10,10	0.037 (± 0.0589)			
calcium,Week 44,n=11,11,6,8,9	0.054 (± 0.1146)			
calcium,Week 48,n=9,8,5,8,5	0.142 (± 0.0782)			
calcium,Week 52,n=9,5,5,5,4	0.083 (± 0.0624)			
Carbon Dioxide,Week 2,n=38,39,26,24,26	0.7 (± 2.24)			
Carbon Dioxide,Week 4,n=37,38,25,23,27	0.1 (± 2.83)			
Carbon Dioxide,Week 8,n=34,31,24,22,23	1.1 (± 2.24)			
Carbon Dioxide,Week 12,n=32,28,24,22,21	1.2 (± 1.73)			
Carbon Dioxide,Week 16,n=28,26,22,19,18	0.5 (± 2.55)			
Carbon Dioxide,Week 20,n=25,23,19,18,16	0.5 (± 2.68)			
Carbon Dioxide,Week 24,n=22,21,16,17,16	-0.2 (± 2.61)			
Carbon Dioxide,Week 28,n=19,18,12,13,14	0.4 (± 3.08)			
Carbon Dioxide,Week 32,n=19,15,10,12,13	0.2 (± 2.24)			
Carbon Dioxide,Week 36,n=15,12,10,12,13	1.0 (± 2.16)			
Carbon Dioxide,Week 40,n=15,11,6,10,10	0.4 (± 1.43)			
Carbon Dioxide,Week 44,n=11,11,6,8,9	-0.1 (± 2.47)			
Carbon Dioxide,Week 48,n=9,8,5,8,5	-0.2 (± 2.17)			
Carbon Dioxide,Week 52,n=9,5,5,5,4	1.8 (± 2.87)			
Chloride,Week 2,n=38,39,26,24,26	0.8 (± 2.77)			
Chloride,Week 4,n=37,38,25,23,27	1.4 (± 2.79)			
Chloride,Week 8,n=34,31,24,22,23	2.1 (± 3.24)			
Chloride,Week 12,n=32,28,24,22,21	2.0 (± 2.36)			
Chloride,Week 16,n=28,26,22,19,18	2.4 (± 3.40)			
Chloride,Week 20,n=25,23,19,18,16	2.5 (± 3.12)			

Chloride, Week 24, n=22, 21, 16, 17, 16	2.3 (± 3.55)			
Chloride, Week 28, n=19, 18, 12, 13, 14	2.9 (± 3.63)			
Chloride, Week 32, n=19, 15, 10, 12, 13	3.4 (± 3.43)			
Chloride, Week 36, n=15, 12, 10, 12, 13	2.8 (± 3.37)			
Chloride, Week 40, n=15, 11, 9, 10, 10	3.9 (± 3.03)			
Chloride, Week 44, n=11, 11, 6, 8, 9	2.2 (± 4.52)			
Chloride, Week 48, n=9, 8, 5, 8, 5	2.8 (± 3.11)			
Chloride, Week 52, n=9, 5, 5, 5, 4	3.8 (± 4.11)			
Glucose, Week 2, n=38, 39, 26, 24, 26	-0.44 (± 3.578)			
Glucose, Week 4, n=37, 38, 25, 23, 27	-0.03 (± 4.387)			
Glucose, Week 8, n=34, 31, 24, 22, 23	-1.15 (± 5.685)			
Glucose, Week 12, n=32, 28, 24, 22, 21	-1.76 (± 5.919)			
Glucose, Week 16, n=28, 26, 22, 19, 18	-1.15 (± 6.411)			
Glucose, Week 20, n=25, 23, 19, 18, 16	-1.96 (± 7.018)			
Glucose, Week 24, n=22, 21, 16, 17, 16	-2.08 (± 6.953)			
Glucose, Week 28, n=19, 18, 12, 13, 14	-2.05 (± 7.699)			
Glucose, Week 32, n=19, 15, 10, 12, 13	-3.12 (± 7.818)			
Glucose, Week 36, n=15, 12, 10, 12, 13	-2.98 (± 7.786)			
Glucose, Week 40, n=15, 11, 9, 10, 10	-0.94 (± 3.589)			
Glucose, Week 44, n=11, 11, 6, 8, 9	-0.23 (± 2.001)			
Glucose, Week 48, n=9, 8, 5, 8, 5	-0.36 (± 2.196)			
Glucose, Week 52, n=9, 5, 5, 5, 4	0.45 (± 2.353)			
Phosphate, Week 2, n=38, 39, 26, 24, 26	0.005 (± 0.1601)			
Phosphate, Week 4, n=37, 38, 25, 23, 27	0.008 (± 0.2087)			
Phosphate, Week 8, n=34, 31, 24, 22, 23	0.055 (± 0.1746)			
Phosphate, Week 12, n=32, 28, 24, 22, 21	0.079 (± 0.1946)			
Phosphate, Week 16, n=28, 26, 22, 19, 18	0.039 (± 0.2238)			
Phosphate, Week 20, n=25, 23, 19, 18, 16	0.060 (± 0.2183)			
Phosphate, Week 24, n=22, 21, 16, 17, 16	0.101 (± 0.1811)			
Phosphate, Week 28, n=19, 18, 12, 13, 14	0.190 (± 0.3143)			
Phosphate, Week 32, n=19, 15, 10, 12, 13	0.155 (± 0.2713)			
Phosphate, Week 36, n=15, 12, 10, 12, 13	0.151 (± 0.2114)			
Phosphate, Week 40, n=15, 11, 6, 10, 10	0.206 (± 0.2151)			
Phosphate, Week 44, n=11, 11, 6, 8, 9	0.218 (± 0.2184)			

Phosphate,Week 48,n=9,8,5,8,5	0.132 (± 0.1972)			
Phosphate,Week 52,n=9,5,5,5,4	0.115 (± 0.1434)			
Potassium,Week 2,n=38,39,26,24,26	0.08 (± 0.375)			
Potassium,Week 4,n=37,38,25,23,27	-0.03 (± 0.343)			
Potassium,Week 8,n=34,31,24,22,23	0.06 (± 0.399)			
Potassium,Week 12,n=32,28,24,22,21	0.04 (± 0.446)			
Potassium,Week 16,n=28,26,22,19,18	0.15 (± 0.279)			
Potassium,Week 20,n=25,23,19,18,16	0.16 (± 0.390)			
Potassium,Week 24,n=22,21,16,17,16	0.16 (± 0.411)			
Potassium,Week 28,n=19,18,12,13,14	0.23 (± 0.418)			
Potassium,Week 32,n=19,15,10,12,13	0.25 (± 0.443)			
Potassium,Week 36,n=15,12,10,12,13	0.21 (± 0.403)			
Potassium,Week 40,n=15,11,9,10,10	0.28 (± 0.355)			
Potassium,Week 44,n=11,11,6,8,9	0.16 (± 0.488)			
Potassium,Week 48,n=9,8,5,8,5	0.52 (± 0.432)			
Potassium,Week 52,n=9,5,5,5,4	0.20 (± 0.365)			
Sodium,Week 2,n=38,39,26,24,26	0.9 (± 2.92)			
Sodium,Week 4,n=37,38,25,23,27	0.6 (± 2.65)			
Sodium,Week 8,n=34,31,24,22,23	1.7 (± 2.91)			
Sodium,Week 12,n=32,28,24,22,21	2.1 (± 2.37)			
Sodium,Week 16,n=28,26,22,19,18	2.3 (± 3.59)			
Sodium,Week 20,n=25,23,19,18,16	2.3 (± 3.52)			
Sodium,Week 24,n=22,21,16,17,16	1.9 (± 2.96)			
Sodium,Week 28,n=19,18,12,13,14	2.4 (± 3.54)			
Sodium,Week 32,n=19,15,10,12,13	3.2 (± 4.13)			
Sodium,Week 36,n=15,12,10,12,13	2.8 (± 3.60)			
Sodium,Week 40,n=15,11,9,10,10	2.9 (± 3.07)			
Sodium,Week 44,n=11,11,6,8,9	1.8 (± 3.77)			
Sodium,Week 48,n=9,8,5,8,5	1.6 (± 2.70)			
Sodium,Week 52,n=9,5,5,5,4	3.5 (± 3.32)			
Urea,Week 2,n=38,39,26,24,26	-0.32 (± 1.240)			
Urea,Week 4,n=37,38,25,23,27	-0.27 (± 1.700)			
Urea,Week 8,n=34,31,24,22,23	-0.34 (± 0.965)			
Urea,Week 12,n=32,28,24,22,21	-0.35 (± 1.316)			
Urea,Week 16,n=28,26,22,19,18	-0.07 (± 1.701)			
Urea,Week 20,n=25,23,19,18,16	-0.77 (± 1.900)			
Urea,Week 24,n=22,21,16,17,16	-0.64 (± 2.019)			
Urea,Week 28,n=19,18,12,13,14	-0.31 (± 1.495)			
Urea,Week 32,n=19,15,10,12,13	0.17 (± 2.609)			
Urea,Week 36,n=15,12,10,12,13	-0.22 (± 2.297)			
Urea,Week 40,n=15,11,9,10,10	0.32 (± 1.886)			
Urea,Week 44,n=11,11,6,8,9	-1.09 (± 1.727)			
Urea,Week 48,n=9,8,5,8,5	0.44 (± 1.282)			

Urea,Week 52,n=9,5,5,5,4	-0.45 (± 1.475)			
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Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in clinical chemistry parameters: Albumin and Protein

End point title	Part A: Change from Baseline in clinical chemistry parameters: Albumin and Protein
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End point description:

Blood samples were collected to analyze the chemistry parameters including Albumin and Protein. Change from Baseline is presented for these parameters. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Grams per liter				
arithmetic mean (standard deviation)				
Albumin,Week 2,n=38,39,26,24,26	0.3 (± 2.29)	0.9 (± 1.79)	0.8 (± 1.88)	-0.9 (± 2.64)
Albumin,Week 4,n=37,38,25,23,27	0.9 (± 2.41)	2.0 (± 2.84)	1.6 (± 1.50)	-1.4 (± 2.46)
Albumin,Week 8,n=34,31,24,22,23	1.9 (± 2.76)	3.1 (± 2.35)	2.1 (± 1.85)	-1.1 (± 2.35)
Albumin,Week 12,n=32,28,24,22,21	2.0 (± 2.26)	3.4 (± 2.50)	3.1 (± 1.54)	-0.5 (± 2.81)
Albumin,Week 16,n=28,26,22,19,18	1.7 (± 2.29)	2.8 (± 2.52)	2.8 (± 2.44)	-1.2 (± 2.41)
Albumin,Week 20,n=25,23,19,18,16	1.8 (± 2.46)	3.9 (± 2.68)	2.8 (± 2.15)	-0.9 (± 2.70)
Albumin,Week 24,n=22,21,16,17,16	1.6 (± 2.77)	3.8 (± 2.36)	3.7 (± 1.85)	0.0 (± 2.83)
Albumin,Week 28,n=19,18,12,13,14	1.5 (± 1.61)	3.5 (± 3.38)	2.4 (± 2.78)	-0.5 (± 2.82)
Albumin,Week 32,n=19,15,10,12,13	2.2 (± 2.03)	3.6 (± 3.68)	2.2 (± 2.66)	-0.7 (± 3.20)
Albumin,Week 36,n=15,12,10,12,13	3.1 (± 2.61)	4.3 (± 3.75)	2.9 (± 2.08)	-1.3 (± 3.25)
Albumin,Week 40,n=15,11,9,10,10	3.2 (± 1.97)	3.9 (± 3.78)	2.4 (± 2.07)	-1.1 (± 2.96)
Albumin,Week 44,n=11,11,6,8,9	3.2 (± 2.36)	4.1 (± 3.36)	2.2 (± 2.23)	0.4 (± 3.07)
Albumin,Week 48,n=9,8,5,8,5	3.4 (± 2.13)	4.4 (± 3.20)	1.6 (± 2.70)	-0.8 (± 3.28)
Albumin,Week 52,n=9,5,5,5,4	3.7 (± 2.45)	5.2 (± 1.64)	4.0 (± 2.55)	-1.2 (± 0.84)
Protein,Week 2,n=38,39,26,24,26	-2.6 (± 3.68)	-2.4 (± 3.13)	-1.9 (± 2.73)	-1.7 (± 3.31)
Protein,Week 4,n=37,38,25,23,27	-2.5 (± 3.49)	-2.4 (± 4.39)	-1.8 (± 2.81)	-2.0 (± 3.64)
Protein,Week 8,n=34,31,24,22,23	-1.9 (± 3.53)	-1.6 (± 4.16)	-2.2 (± 3.67)	-0.7 (± 3.10)
Protein,Week 12,n=32,28,24,22,21	-1.7 (± 3.19)	-1.3 (± 3.72)	-0.8 (± 3.06)	1.0 (± 3.68)
Protein,Week 16,n=28,26,22,19,18	-2.3 (± 3.43)	-2.0 (± 3.67)	-1.9 (± 3.70)	0.2 (± 3.20)

Protein,Week 20,n=25,23,19,18,16	-1.9 (± 3.44)	-0.4 (± 4.69)	-1.3 (± 2.84)	0.6 (± 3.45)
Protein,Week 24,n=22,21,16,17,16	-1.1 (± 3.64)	-0.9 (± 4.39)	0.0 (± 2.85)	1.5 (± 4.86)
Protein,Week 28,n=19,18,12,13,14	-2.4 (± 3.30)	-0.8 (± 5.27)	-2.7 (± 2.67)	-0.2 (± 4.39)
Protein,Week 32,n=19,15,10,12,13	-1.4 (± 3.52)	-1.5 (± 4.67)	-2.1 (± 4.07)	-0.3 (± 4.45)
Protein,Week 36,n=15,12,10,12,13	-0.3 (± 3.48)	-0.8 (± 4.69)	-0.5 (± 2.51)	-0.3 (± 4.11)
Protein,Week 40,n=15,11,9,10,10	-0.5 (± 3.38)	-1.5 (± 4.93)	-2.1 (± 1.76)	-0.4 (± 3.27)
Protein,Week 44,n=11,11,6,8,9	0.3 (± 2.65)	-0.4 (± 4.06)	-2.0 (± 3.52)	2.3 (± 5.50)
Protein,Week 48,n=9,8,5,8,5	0.3 (± 4.69)	-0.1 (± 3.76)	-1.8 (± 4.49)	1.4 (± 4.98)
Protein,Week 52,n=9,5,5,5,4	-0.4 (± 3.54)	1.0 (± 4.69)	0.6 (± 4.88)	-1.0 (± 3.54)

End point values	PartA:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Grams per liter				
arithmetic mean (standard deviation)				
Albumin,Week 2,n=38,39,26,24,26	-0.7 (± 2.24)			
Albumin,Week 4,n=37,38,25,23,27	-0.9 (± 2.46)			
Albumin,Week 8,n=34,31,24,22,23	-0.6 (± 1.80)			
Albumin,Week 12,n=32,28,24,22,21	0.2 (± 1.87)			
Albumin,Week 16,n=28,26,22,19,18	0.6 (± 2.48)			
Albumin,Week 20,n=25,23,19,18,16	0.3 (± 2.11)			
Albumin,Week 24,n=22,21,16,17,16	0.3 (± 1.88)			
Albumin,Week 28,n=19,18,12,13,14	0.4 (± 2.98)			
Albumin,Week 32,n=19,15,10,12,13	1.1 (± 2.93)			
Albumin,Week 36,n=15,12,10,12,13	0.2 (± 3.02)			
Albumin,Week 40,n=15,11,9,10,10	-0.5 (± 2.27)			
Albumin,Week 44,n=11,11,6,8,9	0.6 (± 2.19)			
Albumin,Week 48,n=9,8,5,8,5	2.0 (± 2.92)			
Albumin,Week 52,n=9,5,5,5,4	1.5 (± 4.12)			
Protein,Week 2,n=38,39,26,24,26	-1.7 (± 3.16)			
Protein,Week 4,n=37,38,25,23,27	-2.0 (± 4.05)			
Protein,Week 8,n=34,31,24,22,23	-0.7 (± 3.30)			
Protein,Week 12,n=32,28,24,22,21	0.9 (± 3.67)			
Protein,Week 16,n=28,26,22,19,18	1.0 (± 3.68)			
Protein,Week 20,n=25,23,19,18,16	0.4 (± 2.63)			
Protein,Week 24,n=22,21,16,17,16	0.8 (± 3.09)			
Protein,Week 28,n=19,18,12,13,14	1.6 (± 4.20)			
Protein,Week 32,n=19,15,10,12,13	2.6 (± 3.78)			
Protein,Week 36,n=15,12,10,12,13	1.8 (± 3.51)			
Protein,Week 40,n=15,11,9,10,10	1.4 (± 3.03)			
Protein,Week 44,n=11,11,6,8,9	1.7 (± 2.60)			
Protein,Week 48,n=9,8,5,8,5	3.2 (± 2.28)			
Protein,Week 52,n=9,5,5,5,4	1.8 (± 4.43)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in clinical chemistry parameters: Alanine Aminotransferase (ALT), Alkaline Phosphatase (ALP) and Aspartate Aminotransferase (AST)

End point title	Part A: Change from Baseline in clinical chemistry parameters: Alanine Aminotransferase (ALT), Alkaline Phosphatase (ALP) and Aspartate Aminotransferase (AST)
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End point description:

Blood samples were collected to analyze the chemistry parameters including ALT,ALP and AST. Change from Baseline is presented for these parameters. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT,Week 2,n=38,39,26,24,26	8.2 (± 17.71)	5.3 (± 14.63)	10.1 (± 23.12)	-0.6 (± 3.27)
ALT,Week 4,n=37,38,25,23,27	6.6 (± 11.17)	6.6 (± 16.09)	5.2 (± 6.10)	-1.2 (± 4.20)
ALT,Week 8,n=34,31,24,22,23	6.0 (± 14.70)	9.5 (± 12.71)	4.7 (± 8.25)	-2.8 (± 4.19)
ALT,Week 12,n=32,28,24,22,21	4.7 (± 6.91)	4.4 (± 10.82)	4.0 (± 6.85)	-3.3 (± 5.39)
ALT,Week 16,n=28,26,22,19,18	4.1 (± 8.11)	2.2 (± 9.86)	5.2 (± 10.08)	-3.5 (± 5.23)
ALT,Week 20,n=25,23,19,18,16	16.1 (± 51.67)	4.9 (± 15.83)	8.6 (± 11.73)	2.3 (± 22.33)
ALT,Week 24,n=22,21,16,17,16	8.3 (± 13.62)	2.5 (± 14.71)	16.4 (± 33.68)	-2.8 (± 6.58)
ALT,Week 28,n=19,18,12,13,14	6.7 (± 8.75)	2.9 (± 14.59)	12.1 (± 23.96)	-1.9 (± 3.95)
ALT,Week 32,n=19,15,10,12,13	6.6 (± 11.06)	5.0 (± 14.05)	5.1 (± 9.45)	-2.0 (± 4.45)
ALT,Week 36,n=15,12,10,12,13	8.7 (± 13.58)	6.0 (± 15.22)	4.5 (± 8.44)	-2.8 (± 2.77)
ALT,Week 40,n=15,11,9,10,10	5.3 (± 8.85)	7.3 (± 19.52)	5.4 (± 5.61)	0.1 (± 11.82)
ALT,Week 44,n=11,11,6,8,9	1.8 (± 5.51)	5.5 (± 15.53)	2.7 (± 7.09)	-0.4 (± 7.15)
ALT,Week 48,n=9,8,5,8,5	2.3 (± 6.54)	4.5 (± 16.52)	3.6 (± 10.48)	-3.5 (± 3.12)
ALT,Week 52,n=9,5,5,5,4	1.3 (± 5.98)	1.6 (± 19.63)	8.8 (± 10.03)	-4.4 (± 1.52)
ALP,Week 2,n=38,39,26,24,26	-9.3 (± 15.76)	-11.4 (± 7.46)	-11.4 (± 8.50)	-3.0 (± 5.88)
ALP,Week 4,n=37,38,25,23,27	-15.5 (± 13.96)	-13.4 (± 12.75)	-14.2 (± 10.17)	-2.2 (± 8.83)
ALP,Week 8,n=34,31,24,22,23	-16.8 (± 11.61)	-10.4 (± 13.73)	-15.3 (± 7.14)	2.9 (± 9.95)
ALP,Week 12,n=32,28,24,22,21	-19.2 (± 15.60)	-7.0 (± 10.15)	-15.0 (± 8.06)	6.6 (± 13.21)
ALP,Week 16,n=28,26,22,19,18	-18.2 (± 15.36)	-8.0 (± 12.61)	-14.6 (± 8.56)	1.1 (± 12.90)
ALP,Week 20,n=25,23,19,18,16	-14.4 (± 21.82)	-4.4 (± 12.89)	-13.3 (± 9.58)	5.9 (± 19.44)
ALP,Week 24,n=22,21,16,17,16	-16.3 (± 20.32)	-6.2 (± 13.76)	-12.5 (± 9.08)	6.9 (± 16.34)

ALP,Week 28,n=19,18,12,13,14	-17.6 (± 23.06)	-4.3 (± 14.99)	-17.5 (± 6.56)	1.6 (± 13.28)
ALP,Week 32,n=19,15,10,12,13	-15.9 (± 22.94)	-6.1 (± 11.89)	-12.6 (± 6.93)	-2.3 (± 17.00)
ALP,Week 36,n=15,12,10,12,13	-20.3 (± 24.22)	-7.3 (± 11.18)	-9.6 (± 12.51)	-1.8 (± 15.49)
ALP,Week 40,n=15,11,9,10,10	-14.5 (± 22.71)	-7.4 (± 10.16)	-9.9 (± 11.35)	-0.2 (± 15.17)
ALP,Week 44,n=11,11,6,8,9	-19.4 (± 24.30)	-6.2 (± 13.48)	-4.0 (± 10.86)	2.8 (± 19.93)
ALP,Week 48,n=9,8,5,8,5	-24.4 (± 28.77)	-6.5 (± 8.45)	-4.4 (± 12.82)	1.5 (± 18.31)
ALP,Week 52,n=9,5,5,5,4	-26.0 (± 29.20)	-8.0 (± 9.14)	-3.6 (± 7.60)	1.0 (± 19.34)
AST,Week 2,n=38,39,26,24,26	6.1 (± 8.07)	3.7 (± 4.81)	4.5 (± 7.11)	-0.3 (± 2.66)
AST,Week 4,n=37,38,25,23,27	5.4 (± 8.43)	5.9 (± 6.74)	5.0 (± 3.96)	-1.0 (± 2.75)
AST,Week 8,n=34,31,24,22,23	6.4 (± 6.43)	10.6 (± 8.90)	6.7 (± 7.90)	0.1 (± 2.74)
AST,Week 12,n=32,28,24,22,21	7.6 (± 9.02)	9.0 (± 5.64)	6.5 (± 5.24)	0.5 (± 3.62)
AST,Week 16,n=28,26,22,19,18	8.5 (± 8.94)	7.0 (± 5.79)	8.0 (± 7.28)	0.2 (± 4.45)
AST,Week 20,n=25,23,19,18,16	14.6 (± 27.52)	7.7 (± 7.24)	9.0 (± 7.46)	4.3 (± 20.22)
AST,Week 24,n=22,21,16,17,16	9.8 (± 8.52)	7.6 (± 6.75)	10.5 (± 10.02)	0.6 (± 4.40)
AST,Week 28,n=19,18,12,13,14	9.0 (± 7.23)	8.1 (± 7.30)	9.4 (± 10.61)	1.1 (± 3.88)
AST,Week 32,n=19,15,10,12,13	8.8 (± 7.63)	9.2 (± 7.72)	8.0 (± 4.94)	0.6 (± 3.65)
AST,Week 36,n=15,12,10,12,13	10.6 (± 8.85)	10.8 (± 8.09)	7.6 (± 5.02)	1.3 (± 2.56)
AST,Week 40,n=15,11,9,10,10	8.9 (± 4.56)	8.7 (± 10.82)	9.1 (± 4.11)	4.7 (± 13.17)
AST,Week 44,n=11,11,6,8,9	8.1 (± 3.56)	9.2 (± 8.91)	8.3 (± 5.09)	3.5 (± 4.81)
AST,Week 48,n=9,8,5,8,5	8.1 (± 4.04)	11.8 (± 12.63)	9.8 (± 7.29)	1.3 (± 4.68)
AST,Week 52,n=9,5,5,5,4	7.1 (± 3.33)	9.2 (± 4.97)	11.6 (± 5.68)	-0.2 (± 3.63)

End point values	PartA:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT,Week 2,n=38,39,26,24,26	1.8 (± 15.16)			
ALT,Week 4,n=37,38,25,23,27	-3.1 (± 9.80)			
ALT,Week 8,n=34,31,24,22,23	-6.8 (± 12.81)			
ALT,Week 12,n=32,28,24,22,21	-7.0 (± 11.88)			
ALT,Week 16,n=28,26,22,19,18	-6.6 (± 14.22)			
ALT,Week 20,n=25,23,19,18,16	-8.1 (± 14.38)			
ALT,Week 24,n=22,21,16,17,16	-9.4 (± 13.61)			
ALT,Week 28,n=19,18,12,13,14	-8.9 (± 12.65)			
ALT,Week 32,n=19,15,10,12,13	-10.0 (± 12.40)			
ALT,Week 36,n=15,12,10,12,13	-10.0 (± 13.87)			
ALT,Week 40,n=15,11,9,10,10	-2.1 (± 6.77)			
ALT,Week 44,n=11,11,6,8,9	-7.0 (± 4.42)			
ALT,Week 48,n=9,8,5,8,5	0.2 (± 11.50)			
ALT,Week 52,n=9,5,5,5,4	5.3 (± 20.81)			

ALP,Week 2,n=38,39,26,24,26	-2.6 (± 5.81)			
ALP,Week 4,n=37,38,25,23,27	5.3 (± 27.51)			
ALP,Week 8,n=34,31,24,22,23	1.6 (± 33.37)			
ALP,Week 12,n=32,28,24,22,21	-5.3 (± 16.83)			
ALP,Week 16,n=28,26,22,19,18	-0.3 (± 14.43)			
ALP,Week 20,n=25,23,19,18,16	-1.0 (± 12.41)			
ALP,Week 24,n=22,21,16,17,16	-1.8 (± 20.27)			
ALP,Week 28,n=19,18,12,13,14	2.9 (± 19.72)			
ALP,Week 32,n=19,15,10,12,13	5.2 (± 18.44)			
ALP,Week 36,n=15,12,10,12,13	7.3 (± 20.95)			
ALP,Week 40,n=15,11,9,10,10	12.3 (± 24.69)			
ALP,Week 44,n=11,11,6,8,9	11.9 (± 24.93)			
ALP,Week 48,n=9,8,5,8,5	7.2 (± 17.06)			
ALP,Week 52,n=9,5,5,5,4	-1.5 (± 11.00)			
AST,Week 2,n=38,39,26,24,26	0.4 (± 6.18)			
AST,Week 4,n=37,38,25,23,27	-0.7 (± 7.10)			
AST,Week 8,n=34,31,24,22,23	-1.6 (± 7.72)			
AST,Week 12,n=32,28,24,22,21	0.1 (± 8.74)			
AST,Week 16,n=28,26,22,19,18	1.0 (± 11.88)			
AST,Week 20,n=25,23,19,18,16	1.4 (± 12.10)			
AST,Week 24,n=22,21,16,17,16	-1.3 (± 8.29)			
AST,Week 28,n=19,18,12,13,14	-0.1 (± 9.01)			
AST,Week 32,n=19,15,10,12,13	1.2 (± 9.49)			
AST,Week 36,n=15,12,10,12,13	0.2 (± 9.27)			
AST,Week 40,n=15,11,9,10,10	6.7 (± 11.36)			
AST,Week 44,n=11,11,6,8,9	2.3 (± 3.24)			
AST,Week 48,n=9,8,5,8,5	6.4 (± 5.59)			
AST,Week 52,n=9,5,5,5,4	4.3 (± 6.85)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in clinical chemistry parameters: Bilirubin, Creatinine, Direct Bilirubin and Indirect Bilirubin

End point title	Part A: Change from Baseline in clinical chemistry parameters: Bilirubin, Creatinine, Direct Bilirubin and Indirect Bilirubin
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End point description:

Blood samples were collected to analyze the chemistry parameters including bilirubin, creatinine, direct bilirubin and indirect bilirubin. Baseline was defined as the last non-missing value before first SC IP intake. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	26	27
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin,Week 2,n=38,39,26,24,26	1.8 (± 2.73)	1.5 (± 3.12)	1.9 (± 3.73)	-1.1 (± 1.94)
Bilirubin,Week 4,n=37,38,25,23,27	2.4 (± 5.05)	1.9 (± 3.10)	1.8 (± 2.76)	-1.8 (± 2.52)
Bilirubin,Week 8,n=34,31,24,22,23	3.0 (± 3.58)	2.8 (± 4.81)	0.9 (± 2.95)	-2.3 (± 2.50)
Bilirubin,Week 12,n=32,28,24,22,21	4.3 (± 8.49)	2.8 (± 3.58)	2.7 (± 3.44)	-1.0 (± 2.40)
Bilirubin,Week 16,n=28,26,22,19,18	2.7 (± 4.68)	4.4 (± 4.53)	3.9 (± 3.50)	-0.9 (± 1.85)
Bilirubin,Week 20,n=25,23,19,18,16	4.7 (± 9.09)	4.3 (± 4.36)	3.6 (± 3.58)	-1.4 (± 2.20)
Bilirubin,Week 24,n=22,21,16,17,16	4.9 (± 6.29)	3.0 (± 4.41)	4.8 (± 3.60)	-1.1 (± 1.80)
Bilirubin,Week 28,n=19,18,12,13,14	4.4 (± 5.86)	3.7 (± 3.77)	3.1 (± 3.18)	-0.8 (± 1.92)
Bilirubin,Week 32,n=19,15,10,12,13	4.2 (± 4.95)	4.0 (± 4.54)	2.7 (± 2.91)	-0.8 (± 2.53)
Bilirubin,Week 36,n=15,12,10,12,13	5.2 (± 4.66)	5.3 (± 5.42)	2.3 (± 2.91)	-0.9 (± 1.88)
Bilirubin,Week 40,n=15,11,6,10,10	5.1 (± 4.18)	2.9 (± 4.13)	2.6 (± 2.07)	-1.1 (± 2.02)
Bilirubin,Week 44,n=11,11,6,8,9	4.4 (± 6.14)	1.8 (± 3.52)	2.5 (± 2.17)	-0.1 (± 2.03)
Bilirubin,Week 48,n=9,8,5,8,5	6.7 (± 6.22)	3.8 (± 3.62)	2.2 (± 1.79)	-1.1 (± 1.96)
Bilirubin,Week 52,n=9,5,5,5,4	4.8 (± 5.09)	1.6 (± 3.58)	5.0 (± 4.36)	-1.0 (± 2.00)
Direct Bilirubin,Week 2,n=38,39,26,24,26	0.1 (± 1.03)	-0.1 (± 0.92)	0.1 (± 0.82)	0.0 (± 0.59)
Direct Bilirubin,Week 4,n=37,38,25,23,27	0.3 (± 0.97)	0.1 (± 0.73)	0.1 (± 0.76)	-0.2 (± 0.83)
Direct Bilirubin,Week 8,n=34,31,24,22,23	0.2 (± 1.01)	0.1 (± 0.72)	0.0 (± 0.29)	-0.1 (± 0.75)
Direct Bilirubin,Week 12,n=32,28,24,22,21	0.3 (± 1.12)	0.1 (± 0.66)	0.2 (± 0.96)	-0.1 (± 0.75)
Direct Bilirubin,Week 16,n=28,26,22,19,18	0.3 (± 1.19)	0.4 (± 0.98)	0.3 (± 0.63)	-0.1 (± 0.46)
Direct Bilirubin,Week 20,n=25,23,19,18,16	1.4 (± 3.29)	0.1 (± 1.12)	0.4 (± 0.77)	-0.2 (± 0.65)
Direct Bilirubin,Week 24,n=22,21,16,17,16	1.0 (± 1.59)	0.0 (± 0.89)	0.4 (± 0.81)	-0.4 (± 0.79)
Direct Bilirubin,Week 28,n=19,18,12,13,14	0.7 (± 1.34)	-0.1 (± 1.08)	0.1 (± 0.90)	-0.5 (± 0.88)
Direct Bilirubin,Week 32,n=19,15,10,12,13	0.5 (± 1.26)	0.3 (± 1.03)	0.1 (± 0.32)	-0.2 (± 0.58)
Direct Bilirubin,Week 36,n=15,12,10,12,13	0.7 (± 1.22)	0.3 (± 1.44)	-0.1 (± 0.74)	-0.2 (± 0.58)
Direct Bilirubin,Week 40,n=15,11,6,10,10	0.6 (± 1.18)	-0.4 (± 0.81)	-0.3 (± 0.71)	0.0 (± 0.00)
Direct Bilirubin,Week 44,n=11,11,6,8,9	0.8 (± 0.98)	-0.4 (± 0.81)	0.2 (± 0.41)	0.0 (± 0.00)
Direct Bilirubin,Week 48,n=9,8,5,8,5	1.2 (± 0.97)	-0.3 (± 0.71)	-0.6 (± 1.34)	0.0 (± 0.00)
Direct Bilirubin,Week 52,n=9,5,5,5,4	1.0 (± 1.00)	-0.8 (± 1.10)	-0.2 (± 1.10)	-0.4 (± 0.89)
Indirect Bilirubin,Week 2,n=38,39,26,24,26	1.7 (± 2.51)	1.6 (± 2.84)	1.8 (± 3.18)	-1.1 (± 1.75)
Indirect Bilirubin,Week 4,n=37,38,25,23,27	2.1 (± 4.93)	1.9 (± 2.86)	1.8 (± 2.31)	-1.6 (± 2.19)
Indirect Bilirubin,Week 8,n=34,31,24,22,23	2.8 (± 3.37)	2.7 (± 4.37)	0.9 (± 2.90)	-2.2 (± 2.47)
Indirect Bilirubin,Week 12,n=32,28,24,22,21	4.0 (± 7.94)	2.7 (± 3.28)	2.5 (± 2.87)	-1.0 (± 2.63)
Indirect Bilirubin,Week 16,n=28,26,22,19,18	2.4 (± 4.29)	4.0 (± 3.88)	3.6 (± 3.22)	-0.8 (± 1.84)

Indirect Bilirubin,Week 20,n=25,23,19,18,16	3.3 (± 6.22)	4.2 (± 3.66)	3.2 (± 3.21)	-1.2 (± 2.23)
Indirect Bilirubin,Week 24,n=22,21,16,17,16	4.0 (± 5.52)	3.0 (± 3.88)	4.4 (± 3.03)	-0.8 (± 1.64)
Indirect Bilirubin,Week 28,n=19,18,12,13,14	3.7 (± 5.05)	3.8 (± 3.42)	3.0 (± 3.02)	-0.3 (± 1.80)
Indirect Bilirubin,Week 32,n=19,15,10,12,13	3.7 (± 4.24)	3.7 (± 3.77)	2.6 (± 2.99)	-0.6 (± 2.35)
Indirect Bilirubin,Week 36,n=15,12,10,12,13	4.5 (± 4.02)	5.0 (± 4.47)	2.4 (± 2.63)	-0.8 (± 1.66)
Indirect Bilirubin,Week 40,n=15,11,6,10,10	4.5 (± 3.94)	3.3 (± 3.61)	2.9 (± 2.03)	-1.1 (± 2.02)
Indirect Bilirubin,Week 44,n=11,11,6,8,9	3.5 (± 5.43)	2.2 (± 3.03)	2.3 (± 2.34)	-0.1 (± 2.03)
Indirect Bilirubin,Week 48,n=9,8,5,8,5	5.4 (± 5.68)	4.0 (± 3.21)	2.8 (± 2.28)	-1.1 (± 1.96)
Indirect Bilirubin,Week 52,n=9,5,5,5,4	3.8 (± 4.52)	2.4 (± 2.61)	5.2 (± 5.02)	-0.6 (± 1.95)
Creatinine,Week 2,n=38,39,26,24,26	4.96 (± 9.319)	4.10 (± 12.030)	0.71 (± 5.170)	-1.65 (± 6.165)
Creatinine,,Week 4,n=37,38,25,23,27	4.00 (± 11.061)	3.03 (± 12.685)	2.56 (± 6.760)	-0.64 (± 5.781)
Creatinine,Week 8,n=34,31,24,22,23	3.26 (± 10.522)	1.48 (± 14.285)	0.95 (± 6.027)	-2.93 (± 7.703)
Creatinine,,Week 12,n=32,28,24,22,21	2.88 (± 11.590)	-0.84 (± 16.780)	3.28 (± 6.334)	-3.09 (± 7.615)
Creatinine,,Week 16,n=28,26,22,19,18	3.87 (± 9.387)	1.16 (± 12.971)	1.27 (± 6.604)	-0.14 (± 9.654)
Creatinine,,Week 20,n=25,23,19,18,16	-0.87 (± 8.652)	0.33 (± 9.278)	-0.09 (± 5.721)	-0.18 (± 6.991)
Creatinine,Week 24,n=22,21,16,17,16	1.58 (± 9.671)	-0.45 (± 20.542)	1.86 (± 9.364)	-1.14 (± 8.093)
Creatinine,,Week 28,n=19,18,12,13,14	5.00 (± 12.803)	0.46 (± 17.574)	-1.33 (± 5.372)	-0.28 (± 4.970)
Creatinine, Week 32,n=19,15,10,12,13	3.88 (± 11.182)	-2.52 (± 20.459)	-1.33 (± 7.598)	0.59 (± 7.911)
Creatinine,,Week 36,n=15,12,10,12,13	1.09 (± 11.330)	-3.82 (± 22.270)	0.88 (± 7.151)	4.56 (± 9.011)
Creatinine,,Week 40,n=15,11,6,10,10	4.87 (± 11.617)	-1.45 (± 10.674)	-0.88 (± 9.831)	1.67 (± 9.527)
Creatinine, Week 44,n=11,11,6,8,9	0.03 (± 14.182)	-7.06 (± 19.793)	-2.38 (± 7.847)	0.23 (± 7.876)
Creatinine,,Week 48,n=9,8,5,8,5	7.21 (± 14.144)	-7.15 (± 26.680)	2.80 (± 8.917)	1.43 (± 5.646)
Creatinine,,Week 52,n=9,5,5,5,4	3.56 (± 6.903)	-5.10 (± 30.563)	4.20 (± 9.195)	1.78 (± 9.836)

End point values	PartA:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin,Week 2,n=38,39,26,24,26	-1.0 (± 3.45)			
Bilirubin,Week 4,n=37,38,25,23,27	-1.5 (± 5.22)			
Bilirubin,Week 8,n=34,31,24,22,23	-3.2 (± 5.31)			
Bilirubin,Week 12,n=32,28,24,22,21	-2.9 (± 4.52)			

Bilirubin,Week 16,n=28,26,22,19,18	-3.3 (± 4.25)			
Bilirubin,Week 20,n=25,23,19,18,16	-3.1 (± 4.67)			
Bilirubin,Week 24,n=22,21,16,17,16	-1.7 (± 3.34)			
Bilirubin,Week 28,n=19,18,12,13,14	-3.2 (± 3.72)			
Bilirubin,Week 32,n=19,15,10,12,13	-3.0 (± 3.74)			
Bilirubin,Week 36,n=15,12,10,12,13	-2.1 (± 4.91)			
Bilirubin,Week 40,n=15,11,6,10,10	-1.9 (± 4.18)			
Bilirubin,Week 44,n=11,11,6,8,9	-1.2 (± 3.23)			
Bilirubin,Week 48,n=9,8,5,8,5	-1.8 (± 2.49)			
Bilirubin,Week 52,n=9,5,5,5,4	1.8 (± 6.85)			
Direct Bilirubin,Week 2,n=38,39,26,24,26	-0.3 (± 0.75)			
Direct Bilirubin,Week 4,n=37,38,25,23,27	-0.6 (± 1.31)			
Direct Bilirubin,Week 8,n=34,31,24,22,23	-0.8 (± 1.31)			
Direct Bilirubin,Week 12,n=32,28,24,22,21	-0.6 (± 1.29)			
Direct Bilirubin,Week 16,n=28,26,22,19,18	-0.8 (± 1.40)			
Direct Bilirubin,Week 20,n=25,23,19,18,16	-0.9 (± 1.45)			
Direct Bilirubin,Week 24,n=22,21,16,17,16	-0.8 (± 1.24)			
Direct Bilirubin,Week 28,n=19,18,12,13,14	-1.0 (± 1.52)			
Direct Bilirubin,Week 32,n=19,15,10,12,13	-1.2 (± 1.54)			
Direct Bilirubin,Week 36,n=15,12,10,12,13	-1.2 (± 1.54)			
Direct Bilirubin,Week 40,n=15,11,6,10,10	-1.4 (± 1.35)			
Direct Bilirubin,Week 44,n=11,11,6,8,9	-0.7 (± 1.00)			
Direct Bilirubin,Week 48,n=9,8,5,8,5	-1.2 (± 1.10)			
Direct Bilirubin,Week 52,n=9,5,5,5,4	-0.5 (± 1.00)			
Indirect Bilirubin,Week 2,n=38,39,26,24,26	-0.7 (± 3.19)			
Indirect Bilirubin,Week 4,n=37,38,25,23,27	-0.9 (± 4.27)			
Indirect Bilirubin,Week 8,n=34,31,24,22,23	-2.4 (± 4.34)			
Indirect Bilirubin,Week 12,n=32,28,24,22,21	-2.3 (± 3.79)			
Indirect Bilirubin,Week 16,n=28,26,22,19,18	-2.5 (± 3.00)			
Indirect Bilirubin,Week 20,n=25,23,19,18,16	-2.2 (± 3.47)			
Indirect Bilirubin,Week 24,n=22,21,16,17,16	-0.9 (± 2.62)			
Indirect Bilirubin,Week 28,n=19,18,12,13,14	-2.2 (± 2.55)			
Indirect Bilirubin,Week 32,n=19,15,10,12,13	-1.8 (± 2.52)			
Indirect Bilirubin,Week 36,n=15,12,10,12,13	-0.8 (± 3.83)			
Indirect Bilirubin,Week 40,n=15,11,6,10,10	-0.5 (± 2.95)			
Indirect Bilirubin,Week 44,n=11,11,6,8,9	-0.6 (± 2.88)			

Indirect Bilirubin,Week 48,n=9,8,5,8,5	-0.6 (± 2.19)			
Indirect Bilirubin,Week 52,n=9,5,5,5,4	2.3 (± 6.13)			
Creatinine,Week 2,n=38,39,26,24,26	0.28 (± 7.485)			
Creatinine,,Week 4,n=37,38,25,23,27	0.48 (± 7.222)			
Creatinine,Week 8,n=34,31,24,22,23	2.43 (± 8.688)			
Creatinine,,Week 12,n=32,28,24,22,21	1.46 (± 6.093)			
Creatinine,,Week 16,n=28,26,22,19,18	3.37 (± 15.068)			
Creatinine,,Week 20,n=25,23,19,18,16	4.73 (± 12.179)			
Creatinine,Week 24,n=22,21,16,17,16	2.63 (± 7.834)			
Creatinine,,Week 28,n=19,18,12,13,14	4.07 (± 7.431)			
Creatinine, Week 32,n=19,15,10,12,13	4.10 (± 7.264)			
Creatinine,,Week 36,n=15,12,10,12,13	3.62 (± 11.433)			
Creatinine,,Week 40,n=15,11,6,10,10	1.55 (± 10.630)			
Creatinine, Week 44,n=11,11,6,8,9	3.96 (± 14.656)			
Creatinine,,Week 48,n=9,8,5,8,5	5.72 (± 18.804)			
Creatinine,,Week 52,n=9,5,5,5,4	12.23 (± 16.814)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Mean Serum concentrations of sirukumab

End point title	Part A: Mean Serum concentrations of sirukumab
End point description:	
Blood samples for Pharmacokinetic analysis of sirukumab serum concentrations were planned to be collected at specified time points. Data was not collected due to early termination of the study	
End point type	Secondary
End point timeframe:	
Baseline (Week 0), Weeks 2, 4, 8, 12, 16, 20, 24, 28, 44 and 52	

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[8]	0 ^[9]	0 ^[10]	0 ^[11]
Units: Milligrams per milliliter				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[8] - Data was not collected due to early termination of the study

[9] - Data was not collected due to early termination of the study

[10] - Data was not collected due to early termination of the study

[11] - Data was not collected due to early termination of the study

End point values	PartA:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	0 ^[12]			
Units: Milligrams per milliliter				
arithmetic mean (standard deviation)	()			

Notes:

[12] - Data was not collected due to early termination of the study

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Mean Serum anti-sirukumab antibodies

End point title	Part A: Mean Serum anti-sirukumab antibodies
End point description: Blood samples for Pharmacokinetic analysis of Serum anti-sirukumab antibodies were planned to be collected at specified time points. Data was not collected due to early termination of the study	
End point type	Secondary
End point timeframe: Baseline (Week 0) and up to 52 weeks	

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[13]	0 ^[14]	0 ^[15]	0 ^[16]
Units: Micrograms per milliliter				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[13] - Data was not collected due to early termination of the study

[14] - Data was not collected due to early termination of the study

[15] - Data was not collected due to early termination of the study

[16] - Data was not collected due to early termination of the study

End point values	PartA:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	0 ^[17]			
Units: Micrograms per milliliter				
arithmetic mean (standard deviation)	()			

Notes:

[17] - Data was not collected due to early termination of the study

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in free and total interleukin-6 (IL-6) over time

End point title	Part A: Change from Baseline in free and total interleukin-6 (IL-6) over time
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End point description:

Blood samples for Pharmacodynamic analysis were planned but not collected due to early termination of study.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and up to 52 weeks

End point values	PartA:SIR 100 mg SC q2w+6 month Prednisone	PartA:SIR 100 mg SC q2w+3 month Prednisone	PartA:SIR 50 mg SC q4w+6 month Prednisone	PartA:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[18]	0 ^[19]	0 ^[20]	0 ^[21]
Units: Picograms per milliliter				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[18] - Data was not collected due to early termination of the study

[19] - Data was not collected due to early termination of the study

[20] - Data was not collected due to early termination of the study

[21] - Data was not collected due to early termination of the study

End point values	PartA:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	0 ^[22]			
Units: Picograms per milliliter				
arithmetic mean (standard deviation)	()			

Notes:

[22] - Data was not collected due to early termination of the study

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of participants with AEs, SAEs and corticosteroid related AEs who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Number of participants with AEs, SAEs and corticosteroid related AEs who received at least one dose of 100 mg open-label Sirukumab in Part B
End point description: An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Any untoward event resulting in death, life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, congenital anomaly/birth defect, any other situation according to medical or scientific judgment or all events of possible drug-induced liver injury with hyperbilirubinaemia were categorized as SAE. Number of participants with AEs, SAEs and corticosteroid related AEs for part B have been reported.	
End point type	Secondary
End point timeframe: Up to 120 weeks	

End point values	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone	PartB:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Participants				
number (not applicable)				
All AEs	2	1	1	2
All SAEs	0	0	0	0
Corticosteroid related AEs	0	0	0	1

End point values	PartB:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Participants				
number (not applicable)				
All AEs	2			
All SAEs	0			
Corticosteroid related AEs	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of participants with AEs, SAEs and corticosteroid related AEs who never received 100mg OL Sirukumab in Part B

End point title	Part B: Number of participants with AEs, SAEs and
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End point description:

An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Any untoward event resulting in death, life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, congenital anomaly/birth defect, any other situation according to medical or scientific judgment or all events of possible drug-induced liver injury with hyperbilirubinaemia were categorized as SAE. Number of participants with AEs, SAEs and corticosteroid related AEs for part B have been reported.

End point type	Secondary
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End point timeframe:

Up to 120 weeks

End point values	PartB:Placebo SC q2w + 12 month Prednisone	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Participants				
number (not applicable)				
All AEs	0	4	3	2
All SAEs	0	0	0	0
Corticosteroid related AEs	1	0	1	0

End point values	PartB:Placebo SC q2w + 6 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Participants				
number (not applicable)				
All AEs	1			
All SAEs	0			
Corticosteroid related AEs	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in SBP and DBP for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in SBP and DBP for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
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End point description:

SBP and DBP were measured in semi-supine position after 5 minutes rest for the participant. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL sirukumab is presented.

End point type Secondary

End point timeframe:

Baseline (Week 0) and Weeks 2,4,8,12,14,16,24,36,38,40 and follow up (Week 120)

End point values	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone	PartB:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Millimeters of mercury				
arithmetic mean (standard deviation)				
SBP,Week 2,n=1,1,0,1,2	2.0 (± 99999)	15.0 (± 99999)	99999 (± 99999)	0.0 (± 99999)
SBP,Week 4,n=2,1,1,2,2	5.0 (± 21.21)	0.0 (± 99999)	6.0 (± 99999)	-1.5 (± 3.54)
SBP,Week 8,n=2,1,1,2,1	14.0 (± 8.49)	18.0 (± 99999)	-12.0 (± 99999)	-11.5 (± 10.61)
SBP,Week 12,n=2,1,1,1,0	7.0 (± 1.41)	14.0 (± 99999)	8.0 (± 99999)	2.0 (± 99999)
SBP,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	9.0 (± 99999)
SBP,Week 16,n=2,0,0,1,0	0.0 (± 0.00)	99999 (± 99999)	99999 (± 99999)	11.0 (± 99999)
SBP,Week 24,n=2,0,0,0,0	8.0 (± 0.00)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
SBP,Week 36,n=2,0,0,0,0	11.0 (± 9.90)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
SBP,Week 38,n=1,0,0,0,0	-6.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
SBP,Week 40,n=1,0,0,0,0	-10.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
SBP,Week follow up,n=2,1,0,1,1	3.0 (± 18.38)	-1.0 (± 99999)	99999 (± 99999)	22.0 (± 99999)
DBP,Week 2,n=1,1,0,1,2	-10.0 (± 99999)	-8.0 (± 99999)	99999 (± 99999)	0.0 (± 99999)
DBP,Week 4,n=2,1,1,2,2	-3.0 (± 12.73)	-15.0 (± 99999)	6.0 (± 99999)	2.0 (± 5.66)
DBP,Week 8,n=2,1,1,2,1	3.0 (± 4.24)	-5.0 (± 99999)	-4.0 (± 99999)	4.0 (± 2.83)
DBP,Week 12,n=2,1,1,1,0	-5.0 (± 7.07)	-5.0 (± 99999)	1.0 (± 99999)	4.0 (± 99999)
DBP,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	7.0 (± 99999)
DBP,Week 16,n=2,0,0,1,0	-5.0 (± 7.07)	99999 (± 99999)	99999 (± 99999)	15.0 (± 99999)
DBP,Week 24,n=2,0,0,0,0	1.0 (± 1.41)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
DBP,Week 36,n=2,0,0,0,0	-2.0 (± 2.83)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
DBP,Week 38,n=1,0,0,0,0	-8.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
DBP,Week 40,n=1,0,0,0,0	-10.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

DBP,Week follow up,n=2,1,0,1,1	-2.0 (± 5.66)	-7.0 (± 99999)	99999 (± 99999)	21.0 (± 99999)
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End point values	PartB:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Millimeters of mercury				
arithmetic mean (standard deviation)				
SBP,Week 2,n=1,1,0,1,2	6.5 (± 19.09)			
SBP,Week 4,n=2,1,1,2,2	1.5 (± 0.71)			
SBP,Week 8,n=2,1,1,2,1	5.0 (± 99999)			
SBP,Week 12,n=2,1,1,1,0	99999 (± 99999)			
SBP,Week 14,n=0,0,0,1,0	99999 (± 99999)			
SBP,Week 16,n=2,0,0,1,0	99999 (± 99999)			
SBP,Week 24,n=2,0,0,0,0	99999 (± 99999)			
SBP,Week 36,n=2,0,0,0,0	99999 (± 99999)			
SBP,Week 38,n=1,0,0,0,0	99999 (± 99999)			
SBP,Week 40,n=1,0,0,0,0	99999 (± 99999)			
SBP,Week follow up,n=2,1,0,1,1	12.0 (± 99999)			
DBP,Week 2,n=1,1,0,1,2	7.0 (± 9.90)			
DBP,Week 4,n=2,1,1,2,2	4.5 (± 3.54)			
DBP,Week 8,n=2,1,1,2,1	-1.0 (± 99999)			
DBP,Week 12,n=2,1,1,1,0	99999 (± 99999)			
DBP,Week 14,n=0,0,0,1,0	99999 (± 99999)			
DBP,Week 16,n=2,0,0,1,0	99999 (± 99999)			
DBP,Week 24,n=2,0,0,0,0	99999 (± 99999)			
DBP,Week 36,n=2,0,0,0,0	99999 (± 99999)			
DBP,Week 38,n=1,0,0,0,0	99999 (± 99999)			
DBP,Week 40,n=1,0,0,0,0	99999 (± 99999)			
DBP,Week follow up,n=2,1,0,1,1	3.0 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in SBP and DBP for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in SBP and DBP for participants who never received 100 mg open label Sirukumab in Part B
End point description:	
SBP and DBP were measured in semi-supine position after 5 minutes rest for the participant. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented.	
End point type	Secondary
End point timeframe:	
Baseline (Week 0) and Weeks 4,8,12,16,24,36 and follow up (Week 120)	

End point values	PartB:Placebo SC q2w + 12 month Prednisone	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Millimeters of mercury				
arithmetic mean (standard deviation)				
SBP,Week 4,n=3,3,3,1,2	-2.0 (± 8.49)	-23.7 (± 4.73)	-6.3 (± 5.51)	7.0 (± 25.36)
SBP,Week 8,n=2,1,2,0,2	-1.5 (± 0.71)	-32.5 (± 14.85)	-6.0 (± 99999)	-7.5 (± 17.68)
SBP,Week 12,n=1,1,1,1,1	-2.0 (± 99999)	-59.0 (± 99999)	-4.0 (± 99999)	15.0 (± 99999)
SBP,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-8.0 (± 99999)	25.0 (± 99999)
SBP,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	4.0 (± 99999)	99999 (± 99999)
SBP,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-26.0 (± 99999)	99999 (± 99999)
SBP,Week follow up,n=5,4,2,3,2	5.0 (± 1.41)	-7.4 (± 19.62)	-3.3 (± 8.54)	-17.5 (± 31.82)
DBP,Week 4,n=3,3,3,1,2	-11.0 (± 11.31)	-8.3 (± 14.29)	0.3 (± 4.51)	7.7 (± 8.74)
DBP,Week 8,n=2,1,2,0,2	-6.0 (± 8.49)	-9.0 (± 2.83)	-10.0 (± 99999)	16.5 (± 2.12)
DBP,Week 12,n=1,1,1,1,1	-9.0 (± 99999)	-22.0 (± 99999)	-6.0 (± 99999)	15.0 (± 99999)
DBP,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)	15.0 (± 99999)
DBP,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-10.0 (± 99999)	99999 (± 99999)
DBP,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-10.0 (± 99999)	99999 (± 99999)
DBP,Week follow up,n=5,4,2,3,2	-2.0 (± 4.24)	3.4 (± 12.34)	-2.8 (± 99999)	12.5 (± 10.61)

End point values	PartB:Placebo SC q2w + 6 month Prednisone			
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Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Millimeters of mercury				
arithmetic mean (standard deviation)				
SBP,Week 4,n=3,3,3,1,2	10.0 (± 99999)			
SBP,Week 8,n=2,1,2,0,2	99999 (± 99999)			
SBP,Week 12,n=1,1,1,1,1	13.0 (± 99999)			
SBP,Week 16,n=0,1,1,1,0	-8.0 (± 99999)			
SBP,Week 24,n=0,1,0,0,0	99999 (± 99999)			
SBP,Week 36,n=0,1,0,0,0	99999 (± 99999)			
SBP,Week follow up,n=5,4,2,3,2	10.7 (± 10.07)			
DBP,Week 4,n=3,3,3,1,2	-4.0 (± 99999)			
DBP,Week 8,n=2,1,2,0,2	99999 (± 99999)			
DBP,Week 12,n=1,1,1,1,1	8.0 (± 99999)			
DBP,Week 16,n=0,1,1,1,0	-17.0 (± 99999)			
DBP,Week 24,n=0,1,0,0,0	99999 (± 99999)			
DBP,Week 36,n=0,1,0,0,0	99999 (± 99999)			
DBP,Week follow up,n=5,4,2,3,2	6.0 (± 4.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in Pulse Rate for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in Pulse Rate for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
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End point description:

Pulse rate was measured in semi-supine position after 5 minutes rest. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL sirukumab is presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2,4,8,12,14,16,24,36,38,40 and follow up (Week 120)

End point values	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone	PartB:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: beats per minute				

arithmetic mean (standard deviation)				
Week 2,n=1,1,0,1,2	4.0 (± 99999)	7.0 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Week 4,n=2,1,1,2,2	-2.0 (± 8.49)	6.0 (± 99999)	-10.0 (± 99999)	-17.0 (± 2.83)
Week 8,n=2,1,1,2,1	0.0 (± 5.66)	3.0 (± 999999)	4.0 (± 99999)	-12.5 (± 9.19)
Week 12,n=2,1,1,1,0	-2.0 (± 2.83)	2.0 (± 999999)	4.0 (± 99999)	-12.0 (± 99999)
Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	-24.0 (± 99999)
Week 16,n=2,0,0,1,0	2.0 (± 2.83)	99999 (± 99999)	99999 (± 99999)	-14.0 (± 99999)
Week 24,n=2,0,0,0,0	5.0 (± 1.41)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 36,n=2,0,0,0,0	-2.0 (± 8.49)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 38,n=1,0,0,0,0	0.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 40,n=1,0,0,0,0	0.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week follow up,n=2,1,0,1,1	5.0 (± 12.73)	-3.0 (± 99999)	99999 (± 99999)	-22.0 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: beats per minute				
arithmetic mean (standard deviation)				
Week 2,n=1,1,0,1,2	4.0 (± 8.49)			
Week 4,n=2,1,1,2,2	-5.5 (± 9.19)			
Week 8,n=2,1,1,2,1	-4.0 (± 99999)			
Week 12,n=2,1,1,1,0	99999 (± 99999)			
Week 14,n=0,0,0,1,0	99999 (± 99999)			
Week 16,n=2,0,0,1,0	99999 (± 99999)			
Week 24,n=2,0,0,0,0	99999 (± 99999)			
Week 36,n=2,0,0,0,0	99999 (± 99999)			
Week 38,n=1,0,0,0,0	99999 (± 99999)			
Week 40,n=1,0,0,0,0	99999 (± 99999)			
Week follow up,n=2,1,0,1,1	99999 (± 99999)			

Statistical analyses

Secondary: Part B: Change from Baseline in Pulse Rate for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in Pulse Rate for participants who never received 100 mg open label Sirukumab in Part B
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End point description:

Pulse rate was measured in semi-supine position after 5 minutes rest.. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab is presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 4,8,12,16,24,36 and follow up (Week 120)

End point values	PartB:Placebo SC q2w + 12 month Prednisone	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: beats per minute				
arithmetic mean (standard deviation)				
Week 4,n=3,3,3,1,2	-1.5 (± 6.36)	3.7 (± 1.53)	0.3 (± 3.51)	-14.7 (± 2.31)
Week 8,n=2,1,2,0,2	-0.5 (± 0.71)	8.0 (± 4.24)	4.0 (± 99999)	-5.5 (± 2.12)
Week 12,n=1,1,1,1,1	99999 (± 99999)	11.0 (± 99999)	-4.0 (± 99999)	4.0 (± 99999)
Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-4.0 (± 99999)	-4.0 (± 99999)
Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)	99999 (± 99999)
Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)	99999 (± 99999)
Week follow up,n=5,4,2,3,2	7.5 (± 4.95)	1.4 (± 10.11)	4.0 (± 99999)	-1.5 (± 2.12)

End point values	PartB:Placebo SC q2w + 6 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: beats per minute				
arithmetic mean (standard deviation)				
Week 4,n=3,3,3,1,2	-29.0 (± 99999)			
Week 8,n=2,1,2,0,2	99999 (± 99999)			
Week 12,n=1,1,1,1,1	6.0 (± 99999)			
Week 16,n=0,1,1,1,0	6.0 (± 99999)			
Week 24,n=0,1,0,0,0	99999 (± 99999)			

Week 36,n=0,1,0,0,0	99999 (± 99999)			
Week follow up,n=5,4,2,3,2	-7.7 (± 17.62)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in Temperature for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in Temperature for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
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End point description:

Temperature was measured in semi-supine position after 5 minutes rest.. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL sirukumab is presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2,4,8,12,14,16,24,36,38,40 and follow up (Week 120)

End point values	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone	PartB:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Celsius				
arithmetic mean (standard deviation)				
Week 2,n=1,1,0,1,2	0.20 (± 99999)	0.50 (± 99999)	99999 (± 99999)	-0.40 (± 99999)
Week 4,n=2,1,1,2,2	0.15 (± 0.071)	-0.50 (± 99999)	-0.30 (± 99999)	-0.10 (± 0.141)
Week 8,n=2,1,1,2,1	-0.15 (± 0.212)	0.00 (± 99999)	0.10 (± 99999)	-0.20 (± 0.000)
Week 12,n=2,1,1,1,0	-0.25 (± 0.071)	0.90 (± 99999)	0.50 (± 99999)	0.00 (± 99999)
Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	-0.20 (± 99999)
Week 16,n=2,0,0,1,0	-0.05 (± 0.071)	99999 (± 99999)	99999 (± 99999)	-0.10 (± 99999)
Week 24,n=2,0,0,0,0	-0.42 (± 0.163)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 36,n=2,0,0,0,0	-0.25 (± 0.071)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 38,n=1,0,0,0,0	0.00 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 40,n=1,0,0,0,0	0.00 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week follow up,n=2,1,0,1,1	0.15 (± 0.071)	0.00 (± 99999)	99999 (± 99999)	0.50 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Celsius				
arithmetic mean (standard deviation)				
Week 2,n=1,1,0,1,2	-0.65 (± 0.071)			
Week 4,n=2,1,1,2,2	0.30 (± 1.414)			
Week 8,n=2,1,1,2,1	-0.50 (± 99999)			
Week 12,n=2,1,1,1,0	99999 (± 99999)			
Week 14,n=0,0,0,1,0	99999 (± 99999)			
Week 16,n=2,0,0,1,0	99999 (± 99999)			
Week 24,n=2,0,0,0,0	99999 (± 99999)			
Week 36,n=2,0,0,0,0	99999 (± 99999)			
Week 38,n=1,0,0,0,0	99999 (± 99999)			
Week 40,n=1,0,0,0,0	99999 (± 99999)			
Week follow up,n=2,1,0,1,1	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in Temperature for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in Temperature for participants who never received 100 mg open label Sirukumab in Part B
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End point description:

Temperature was measured in semi-supine position after 5 minutes rest.. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 4,8,12,16,24,36 and follow up (Week 120)

End point values	PartB:Placebo SC q2w + 12 month Prednisone	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Celsius				
arithmetic mean (standard deviation)				
Week 4,n=3,3,3,1,2	0.10 (± 0.283)	0.10 (± 0.458)	0.07 (± 0.115)	0.00 (± 0.300)
Week 8,n=2,1,2,0,2	0.05 (± 0.354)	-0.10 (± 0.566)	0.00 (± 99999)	-0.10 (± 0.283)
Week 12,n=1,1,1,1,1	-0.50 (± 99999)	-0.30 (± 99999)	0.40 (± 99999)	0.00 (± 99999)
Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	0.20 (± 99999)	0.00 (± 99999)
Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.00 (± 99999)	99999 (± 99999)
Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.00 (± 99999)	99999 (± 99999)
Week follow up,n=5,4,2,3,2	0.20 (± 0.283)	0.06 (± 0.305)	0.15 (± 0.265)	0.00 (± 0.283)

End point values	PartB:Placebo SC q2w + 6 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Celsius				
arithmetic mean (standard deviation)				
Week 4,n=3,3,3,1,2	-0.20 (± 99999)			
Week 8,n=2,1,2,0,2	99999 (± 99999)			
Week 12,n=1,1,1,1,1	0.00 (± 99999)			
Week 16,n=0,1,1,1,0	-0.10 (± 99999)			
Week 24,n=0,1,0,0,0	99999 (± 99999)			
Week 36,n=0,1,0,0,0	99999 (± 99999)			
Week follow up,n=5,4,2,3,2	-0.13 (± 0.252)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameters- Eosinophils, Leukocytes, Lymphocytes, Neutrophils and Platelets for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameters- Eosinophils, Leukocytes, Lymphocytes, Neutrophils and Platelets for participants who received at least one dose of 100
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End point description:

Blood samples were collected to analyze the hematology parameters including Eosinophils, Leukocytes, Lymphocytes, Neutrophils and Platelets. Change from Baseline is presented for these parameters. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL sirukumab is presented.

End point type

Secondary

End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone	PartB:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Giga cells per liter				
arithmetic mean (standard deviation)				
Eosinophils, Week 2, n=1,1,0,1,2	-0.010 (± 99999)	-0.110 (± 99999)	99999 (± 99999)	0.000 (± 99999)
Eosinophils, Week 4, n=2,1,1,2,2	-0.015 (± 0.0212)	-0.210 (± 99999)	-0.010 (± 99999)	-0.030 (± 0.0283)
Eosinophils, Week 8, n=2,1,1,2,1	-0.010 (± 0.0424)	-0.180 (± 99999)	0.040 (± 99999)	-0.120 (± 0.1838)
Eosinophils, Week 12, n=2,0,1,1,0	-0.030 (± 0.0000)	99999 (± 99999)	0.030 (± 99999)	-0.160 (± 99999)
Eosinophils, Week 14, n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	-0.290 (± 99999)
Eosinophils, Week 16, n=2,0,0,1,0	0.030 (± 0.0141)	99999 (± 99999)	99999 (± 99999)	-0.270 (± 99999)
Eosinophils, Week 24, n=2,0,0,0,0	-0.015 (± 0.0212)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Eosinophils, Week 36, n=2,0,0,0,0	-0.010 (± 0.0566)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Eosinophils, Week 38, n=1,0,0,0,0	0.020 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Eosinophils, Week 40, n=1,0,0,0,0	-0.030 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Leukocytes, Week 2, n=1,1,0,1,2	-0.20 (± 99999)	0.30 (± 99999)	99999 (± 99999)	2.60 (± 99999)
Leukocytes, Week 4, n=2,1,1,2,2	0.25 (± 0.778)	-0.30 (± 99999)	0.20 (± 99999)	0.60 (± 1.697)
Leukocytes, Week 8, n=2,1,1,2,1	-0.25 (± 1.061)	0.00 (± 99999)	0.60 (± 99999)	0.10 (± 0.000)
Leukocytes, Week 12, n=2,0,1,1,0	-0.10 (± 0.990)	99999 (± 99999)	0.90 (± 99999)	-0.60 (± 99999)
Leukocytes, Week 14, n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.40 (± 99999)
Leukocytes, Week 16, n=2,0,0,1,0	-0.45 (± 0.778)	99999 (± 99999)	99999 (± 99999)	-0.30 (± 99999)
Leukocytes, Week 24, n=2,0,0,0,0	-0.20 (± 0.424)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Leukocytes, Week 36, n=2,0,0,0,0	0.65 (± 0.354)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Leukocytes, Week 38, n=1,0,0,0,0	-0.50 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Leukocytes,Week 40,n=1,0,0,0,0	-1.30 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Lymphocytes,Week 2,n=1,1,0,1,2	-0.170 (± 99999)	0.000 (± 99999)	99999 (± 99999)	-0.400 (± 99999)
Lymphocytes,Week 4,n=2,1,1,2,2	0.110 (± 0.0566)	-0.340 (± 99999)	-0.010 (± 99999)	-0.035 (± 0.2051)
Lymphocytes,Week 8,n=2,1,1,2,1	-0.120 (± 0.0283)	0.160 (± 99999)	0.050 (± 99999)	-0.185 (± 0.3323)
Lymphocytes,Week 12,n=2,0,1,1,0	-0.030 (± 0.0283)	99999 (± 99999)	0.300 (± 99999)	-0.190 (± 99999)
Lymphocytes,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.490 (± 99999)
Lymphocytes,Week 16,n=2,0,0,1,0	-0.230 (± 0.2828)	99999 (± 99999)	99999 (± 99999)	0.540 (± 99999)
Lymphocytes,Week 24,n=2,0,0,0,0	-0.320 (± 0.1697)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Lymphocytes,Week 36,n=2,0,0,0,0	0.195 (± 0.1768)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
LymphocytesWeek 38,n=1,0,0,0,0	0.010 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Lymphocytes,Week 40,n=1,0,0,0,0	-0.160 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Neutrophils ,Week 2,n=1,1,0,1,2	-0.040 (± 99999)	0.510 (± 99999)	99999 (± 99999)	3.010 (± 99999)
Neutrophils ,Week 4,n=2,1,1,2,2	0.205 (± 0.5728)	0.400 (± 99999)	0.230 (± 99999)	0.740 (± 1.8950)
Neutrophils ,Week 8,n=2,1,1,2,2	-0.265 (± 0.6435)	0.060 (± 99999)	0.620 (± 99999)	0.485 (± 0.1909)
Neutrophils ,Week 12,n=2,0,1,1,0	0.020 (± 0.8061)	99999 (± 99999)	0.630 (± 99999)	-0.320 (± 99999)
Neutrophils ,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.590 (± 99999)
Neutrophils ,Week 16,n=2,0,0,1,0	-0.235 (± 0.4879)	99999 (± 99999)	99999 (± 99999)	-0.050 (± 99999)
Neutrophils ,Week 24,n=2,0,0,0,0	0.085 (± 0.6859)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Neutrophils ,Week 36,n=2,0,0,0,0	0.540 (± 0.6788)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Neutrophils ,Week 38,n=1,0,0,0,0	-0.460 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Neutrophils,Week 40,n=1,0,0,0,0	-0.770 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Platelets ,Week 2,n=1,1,0,1,2	5.0 (± 99999)	4.0 (± 99999)	99999 (± 99999)	-27.0 (± 99999)
Platelets,Week 4,n=2,1,1,2,2	-1.0 (± 4.24)	6.0 (± 99999)	-1.0 (± 99999)	-33.5 (± 30.41)
Platelets,Week 8,n=2,1,1,2,1	7.0 (± 11.31)	-6.0 (± 99999)	2.0 (± 99999)	-20.5 (± 28.99)
Platelets,Week 12,n=2,0,1,1,0	7.0 (± 7.07)	99999 (± 99999)	52.0 (± 99999)	12.0 (± 99999)
Platelets,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	-31.0 (± 99999)
Platelets,Week 16,n=2,0,0,1,0	2.0 (± 1.41)	99999 (± 99999)	99999 (± 99999)	-97.0 (± 99999)
Platelets,Week 24,n=2,0,0,0,0	-18.5 (± 9.19)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Platelets,Week 36,n=2,0,0,0,0	10.0 (± 21.21)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Platelets,Week 38,n=1,0,0,0,0	-15.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Platelets,Week 40,n=1,0,0,0,0	-6.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Giga cells per liter				
arithmetic mean (standard deviation)				
Eosinophils,Week 2,n=1,1,0,1,2	-0.010 (± 0.0141)			
Eosinophils,Week 4,n=2,1,1,2,2	0.035 (± 0.0495)			
Eosinophils,Week 8,n=2,1,1,2,1	0.045 (± 0.0636)			
Eosinophils,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Eosinophils,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Eosinophils,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Eosinophils,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Eosinophils,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Eosinophils,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Eosinophils,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Leukocytes,Week 2,n=1,1,0,1,2	-2.30 (± 0.424)			
Leukocytes,Week 4,n=2,1,1,2,2	-1.45 (± 0.071)			
Leukocytes,Week 8,n=2,1,1,2,1	-0.95 (± 2.333)			
Leukocytes,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Leukocytes,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Leukocytes,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Leukocytes,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Leukocytes,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Leukocytes,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Leukocytes,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Lymphocytes,Week 2,n=1,1,0,1,2	-0.160 (± 0.0990)			
Lymphocytes,Week 4,n=2,1,1,2,2	-0.115 (± 0.5162)			
Lymphocytes,Week 8,n=2,1,1,2,1	-0.275 (± 0.4172)			
Lymphocytes,Week 12,n=2,0,1,1,0	99999 (± 99999)			

Lymphocytes,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Lymphocytes,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Lymphocytes,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Lymphocytes,Week 36,n=2,0,0,0,0	99999 (± 99999)			
LymphocytesWeek 38,n=1,0,0,0,0	99999 (± 99999)			
Lymphocytes,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Neutrophils ,Week 2,n=1,1,0,1,2	-2.210 (± 0.5233)			
Neutrophils ,Week 4,n=2,1,1,2,2	-1.420 (± 0.4950)			
Neutrophils ,Week 8,n=2,1,1,2,2	-0.790 (± 1.8385)			
Neutrophils ,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Neutrophils ,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Neutrophils ,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Neutrophils ,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Neutrophils ,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Neutrophils ,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Neutrophils,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Platelets ,Week 2,n=1,1,0,1,2	-20.5 (± 57.28)			
Platelets,Week 4,n=2,1,1,2,2	-42.0 (± 11.31)			
Platelets,Week 8,n=2,1,1,2,1	-40.0 (± 0.00)			
Platelets,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Platelets,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Platelets,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Platelets,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Platelets,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Platelets,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Platelets,Week 40,n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameters- Eosinophils, Leukocytes, Lymphocytes, Neutrophils and Platelets for participants who never

received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameters- Eosinophils, Leukocytes, Lymphocytes, Neutrophils and Platelets for participants who never received 100 mg open label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the hematology parameters including Eosinophils, Leukocytes, Lymphocytes, Neutrophils and Platelets. Change from Baseline is presented for these parameters. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 4,8,12,16,24 and 36

End point values	PartB:Placebo SC q2w + 12 month Prednisone	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Giga cells per liter				
arithmetic mean (standard deviation)				
Eosinophils, Week 4, n=3,3,2,1,2	0.415 (± 0.5869)	-0.110 (± 0.1735)	-0.013 (± 0.0551)	-0.050 (± 0.0849)
Eosinophils, Week 8, n=2,1,2,0,2	0.330 (± 0.4101)	-0.070 (± 0.0707)	0.020 (± 99999)	0.020 (± 0.2546)
Eosinophils, Week 12, n=1,1,1,1,1	0.030 (± 99999)	-0.120 (± 99999)	-0.120 (± 99999)	-0.190 (± 99999)
Eosinophils, Week 16, n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-0.200 (± 99999)	-0.180 (± 99999)
Eosinophils, Week 24, n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.100 (± 99999)	99999 (± 99999)
Eosinophils, Week 36, n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.240 (± 99999)	99999 (± 99999)
Leukocytes, Week 4, n=3,3,2,1,2	1.30 (± 0.990)	0.40 (± 0.500)	0.30 (± 1.229)	0.50 (± 0.000)
Leukocytes, Week 8, n=2,1,2,0,2	0.65 (± 0.071)	0.25 (± 0.071)	0.10 (± 99999)	0.90 (± 0.424)
Leukocytes, Week 12, n=1,1,1,1,1	-0.70 (± 99999)	-1.30 (± 99999)	-1.60 (± 99999)	0.80 (± 99999)
Leukocytes, Week 16, n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-0.50 (± 99999)	0.30 (± 99999)
Leukocytes, Week 24, n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.60 (± 99999)	99999 (± 99999)
Leukocytes, Week 36, n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-1.10 (± 99999)	99999 (± 99999)
Lymphocytes, Week 4, n=3,3,2,1,2	0.015 (± 0.2475)	0.293 (± 0.2136)	0.077 (± 0.2442)	0.370 (± 0.0990)
Lymphocytes, Week 8, n=2,1,2,0,2	-0.180 (± 0.4243)	0.470 (± 0.0707)	0.090 (± 99999)	0.205 (± 0.0495)
Lymphocytes, Week 12, n=1,1,1,1,1	-0.610 (± 99999)	-0.210 (± 99999)	0.140 (± 99999)	0.190 (± 99999)
Lymphocytes, Week 16, n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-0.040 (± 99999)	0.340 (± 99999)
Lymphocytes, Week 24, n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.000 (± 99999)	99999 (± 99999)
Lymphocytes, Week 36, n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.240 (± 99999)	99999 (± 99999)

Neutrophils ,Week 4,n=3,3,2,1,2	0.815 (± 0.0212)	0.183 (± 0.4196)	0.333 (± 1.0108)	0.180 (± 0.1414)
Neutrophils ,Week 8,n=2,1,2,0,2	0.500 (± 0.8627)	-0.205 (± 0.1909)	0.010 (± 99999)	0.600 (± 0.0283)
Neutrophils ,Week 12,n=1,1,1,1,1	-0.140 (± 99999)	-0.750 (± 99999)	-1.440 (± 99999)	0.820 (± 99999)
Neutrophils ,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-0.220 (± 99999)	0.230 (± 99999)
Neutrophils ,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.350 (± 99999)	99999 (± 99999)
Neutrophils ,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.420 (± 99999)	99999 (± 99999)
Platelets,Week 4,n=3,3,2,1,2	-14.0 (± 4.24)	15.0 (± 31.43)	-6.0 (± 9.64)	10.5 (± 3.54)
Platelets,Week 8,n=2,1,2,0,2	31.5 (± 4.95)	17.5 (± 23.33)	-25.0 (± 99999)	10.0 (± 22.63)
Platelets,Week 12,n=1,1,1,1,1	14.0 (± 99999)	27.0 (± 99999)	-20.0 (± 99999)	14.0 (± 99999)
Platelets,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-4.0 (± 99999)	15.0 (± 99999)
Platelets,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-20.0 (± 99999)	99999 (± 99999)
Platelets,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-16.0 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 6 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Giga cells per liter				
arithmetic mean (standard deviation)				
Eosinophils,Week 4,n=3,3,2,1,2	-0.030 (± 99999)			
Eosinophils,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Eosinophils,Week 12,n=1,1,1,1,1	0.070 (± 99999)			
Eosinophils,Week 16,n=0,1,1,1,0	-0.050 (± 99999)			
Eosinophils,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Eosinophils,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Leukocytes,Week 4,n=3,3,2,1,2	-0.40 (± 99999)			
Leukocytes,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Leukocytes,Week 12,n=1,1,1,1,1	-1.50 (± 99999)			
Leukocytes,Week 16,n=0,1,1,1,0	-1.30 (± 99999)			
Leukocytes,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Leukocytes,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Lymphocytes,Week 4,n=3,3,2,1,2	-0.960 (± 99999)			

Lymphocytes,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Lymphocytes,Week 12,n=1,1,1,1,1	0.380 (± 99999)			
Lymphocytes,Week 16,n=0,1,1,1,0	-0.520 (± 99999)			
Lymphocytes,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Lymphocytes,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Neutrophils ,Week 4,n=3,3,2,1,2	0.390 (± 99999)			
Neutrophils ,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Neutrophils ,Week 12,n=1,1,1,1,1	-1.770 (± 99999)			
Neutrophils ,Week 16,n=0,1,1,1,0	-0.210 (± 99999)			
Neutrophils ,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Neutrophils ,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Platelets,Week 4,n=3,3,2,1,2	26.0 (± 99999)			
Platelets,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Platelets,Week 12,n=1,1,1,1,1	-8.0 (± 99999)			
Platelets,Week 16,n=0,1,1,1,0	-19.0 (± 99999)			
Platelets,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Platelets,Week 36,n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameters- MCHC and Hemoglobin for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameters- MCHC and Hemoglobin for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
End point description:	
Blood samples were collected to analyze the hematology parameters including MCHC and Hemoglobin. Change from Baseline is presented for these parameters. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL sirukumab is presented.	
End point type	Secondary
End point timeframe:	
Baseline (Week 0) and Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40	

End point values	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone	PartB:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Grams per liter				
arithmetic mean (standard deviation)				
MCHC,Week 2,n=1,1,0,1,1	-3.0 (± 99999)	-1.0 (± 99999)	99999 (± 99999)	-3.0 (± 99999)
MCHC,Week 4,n=2,1,0,2,1	-1.5 (± 3.54)	1.0 (± 99999)	99999 (± 99999)	3.5 (± 2.12)
MCHC,Week 8,n=2,1,0,2,1	0.0 (± 12.73)	16.0 (± 99999)	99999 (± 99999)	3.5 (± 14.85)
MCHC,Week 12,n=2,0,0,1,0	-5.5 (± 0.71)	99999 (± 99999)	99999 (± 99999)	19.0 (± 99999)
MCHC,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	5.0 (± 99999)
MCHC,Week 16,n=2,0,0,1,0	0.0 (± 1.41)	99999 (± 99999)	99999 (± 99999)	11.0 (± 99999)
MCHC,Week 24,n=2,0,0,0,0	-3.0 (± 2.83)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
MCHC,Week 36,n=2,0,0,0,0	-4.0 (± 4.24)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
MCHC,Week 38,n=1,0,0,0,0	-3.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
MCHC,Week 40,n=1,0,0,0,0	4.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Hemoglobin,Week 2,n=1,1,0,1,2	-4.0 (± 99999)	-2.0 (± 99999)	99999 (± 99999)	7.0 (± 99999)
Hemoglobin,Week 4,n=2,1,1,2,2	0.5 (± 0.71)	-2.0 (± 99999)	-9.0 (± 99999)	-0.5 (± 10.61)
Hemoglobin,Week 8,n=2,1,1,2,1	4.0 (± 1.41)	3.0 (± 99999)	0.0 (± 99999)	-0.5 (± 10.61)
Hemoglobin,Week 12,n=2,0,1,1,0	1.5 (± 3.54)	99999 (± 99999)	0.0 (± 99999)	-6.0 (± 99999)
Hemoglobin,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Hemoglobin,Week 16,n=2,0,0,1,0	0.0 (± 0.00)	99999 (± 99999)	99999 (± 99999)	8.0 (± 99999)
Hemoglobin,Week 24,n=2,0,0,0,0	-0.5 (± 7.78)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Hemoglobin,Week 36,n=2,0,0,0,0	-1.5 (± 3.54)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Hemoglobin,Week 38,n=1,0,0,0,0	-3.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Hemoglobin,Week 40,n=1,0,0,0,0	-3.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Grams per liter				
arithmetic mean (standard deviation)				
MCHC,Week 2,n=1,1,0,1,1	20.0 (± 99999)			
MCHC,Week 4,n=2,1,0,2,1	23.0 (± 99999)			

MCHC,Week 8,n=2,1,0,2,1	9.0 (± 99999)			
MCHC,Week 12,n=2,0,0,1,0	99999 (± 99999)			
MCHC,Week 14,n=0,0,0,1,0	99999 (± 99999)			
MCHC,Week 16,n=2,0,0,1,0	99999 (± 99999)			
MCHC,Week 24,n=2,0,0,0,0	99999 (± 99999)			
MCHC,Week 36,n=2,0,0,0,0	99999 (± 99999)			
MCHC,Week 38,n=1,0,0,0,0	99999 (± 99999)			
MCHC,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Hemoglobin,Week 2,n=1,1,0,1,2	10.0 (± 4.24)			
Hemoglobin,Week 4,n=2,1,1,2,2	8.0 (± 8.49)			
Hemoglobin,Week 8,n=2,1,1,2,1	9.0 (± 4.24)			
Hemoglobin,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Hemoglobin,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Hemoglobin,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Hemoglobin,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Hemoglobin,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Hemoglobin,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Hemoglobin,Week 40,n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameters- MCHC and Hemoglobin for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameters- MCHC and Hemoglobin for participants who never received 100 mg open label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the hematology parameters including MCHC and Hemoglobin. Change from Baseline is presented for these parameters. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 4,8,12,16,24 and 36

End point values	PartB:Placebo SC q2w + 12 month Prednisone	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Grams per liter				
arithmetic mean (standard deviation)				
MCHC,Week 4,n=3,3,2,1,2	-7.0 (± 11.31)	-18.0 (± 99999)	-14.0 (± 4.24)	-3.0 (± 1.41)
MCHC,Week 8,n=0,1,2,0,2	8.0 (± 19.80)	99999 (± 99999)	-8.0 (± 99999)	-0.5 (± 16.26)
MCHC,Week 12,n=0,1,1,1,1	11.0 (± 99999)	99999 (± 99999)	-10.0 (± 99999)	11.0 (± 99999)
MCHC,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-9.0 (± 99999)	-1.0 (± 99999)
MCHC,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-17.0 (± 99999)	99999 (± 99999)
MCHC,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-15.0 (± 99999)	99999 (± 99999)
Hemoglobin,Week 4,n=3,3,2,1,2	-5.5 (± 3.54)	-4.0 (± 5.29)	-6.3 (± 3.51)	2.0 (± 9.90)
Hemoglobin,Week 8,n=2,1,2,0,2	-1.5 (± 10.61)	-6.0 (± 14.14)	-4.0 (± 99999)	4.0 (± 12.73)
Hemoglobin,Week 12,n=1,1,1,1,1	5.0 (± 99999)	-5.0 (± 99999)	-1.0 (± 99999)	20.0 (± 99999)
Hemoglobin,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-2.0 (± 99999)	19.0 (± 99999)
Hemoglobin,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-4.0 (± 99999)	99999 (± 99999)
Hemoglobin,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	2.0 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 6 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Grams per liter				
arithmetic mean (standard deviation)				
MCHC,Week 4,n=3,3,2,1,2	0.0 (± 99999)			
MCHC,Week 8,n=0,1,2,0,2	99999 (± 99999)			
MCHC,Week 12,n=0,1,1,1,1	21.0 (± 99999)			
MCHC,Week 16,n=0,1,1,1,0	8.0 (± 99999)			
MCHC,Week 24,n=0,1,0,0,0	99999 (± 99999)			
MCHC,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Hemoglobin,Week 4,n=3,3,2,1,2	-2.0 (± 99999)			
Hemoglobin,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Hemoglobin,Week 12,n=1,1,1,1,1	8.0 (± 99999)			
Hemoglobin,Week 16,n=0,1,1,1,0	2.0 (± 99999)			
Hemoglobin,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Hemoglobin,Week 36,n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameter-Hematocrit for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameter-Hematocrit for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the hematology parameter Hematocrit. Change from Baseline is presented for this parameter. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL sirukumab is presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone	PartB:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Hematocrit, Week 2, n=1,1,0,1,2	-0.0080 (± 99999)	-0.0060 (± 99999)	99999 (± 99999)	0.0250 (± 99999)
Hematocrit, Week 4, n=2,1,1,2,2	0.0030 (± 0.00141)	-0.0080 (± 99999)	-0.0250 (± 99999)	-0.0060 (± 0.03111)
Hematocrit, Week 8, n=2,1,1,2,2	0.0115 (± 0.01909)	-0.0110 (± 99999)	-0.0030 (± 99999)	-0.0040 (± 0.01414)
Hematocrit, Week 12, n=2,0,1,1,0	0.0125 (± 0.01202)	99999 (± 99999)	-0.0060 (± 99999)	-0.0420 (± 99999)
Hematocrit, Week 14, n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	-0.0080 (± 99999)
Hematocrit, Week 16, n=2,0,0,1,0	0.0000 (± 0.00141)	99999 (± 99999)	99999 (± 99999)	0.0080 (± 99999)
Hematocrit, Week 24, n=2,0,0,0,0	0.0040 (± 0.02687)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Hematocrit, Week 36, n=2,0,0,0,0	0.0005 (± 0.01626)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Hematocrit, Week 38, n=1,0,0,0,0	-0.0050 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Hematocrit, Week 40, n=1,0,0,0,0	-0.0140 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Hematocrit,Week 2,n=1,1,0,1,2	0.0235 (± 0.01202)			
Hematocrit,Week 4,n=2,1,1,2,2	0.0105 (± 0.00354)			
Hematocrit,Week 8,n=2,1,1,2,2	0.0260 (± 0.02546)			
Hematocrit,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Hematocrit,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Hematocrit,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Hematocrit,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Hematocrit,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Hematocrit,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Hematocrit,Week 40,n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameter-Hematocrit for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameter-Hematocrit for participants who never received 100 mg open label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the hematology parameter Hematocrit. Change from Baseline is presented for this parameter. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented.

End point type	Secondary
End point timeframe:	
Baseline (Week 0) and Weeks 4,8,12,16,24 and 36	

End point values	PartB:Placebo SC q2w + 12 month Prednisone	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Hematocrit,Week 4,n=3,3,2,1,2	-0.0070 (± 0.00849)	-0.0047 (± 0.02570)	-0.0057 (± 0.01834)	0.0115 (± 0.02616)
Hematocrit,Week 8,n=2,1,2,0,2	-0.0120 (± 0.00424)	-0.0185 (± 0.04879)	0.0000 (± 99999)	0.0135 (± 0.01768)
Hematocrit,Week 12,n=1,1,1,1,1	0.0030 (± 99999)	-0.0120 (± 99999)	0.0080 (± 99999)	0.0470 (± 99999)
Hematocrit,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	0.0060 (± 99999)	0.0610 (± 99999)
Hematocrit,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.0100 (± 99999)	99999 (± 99999)
Hematocrit,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.0280 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 6 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Hematocrit,Week 4,n=3,3,2,1,2	-0.0040 (± 99999)			
Hematocrit,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Hematocrit,Week 12,n=1,1,1,1,1	-0.0010 (± 99999)			
Hematocrit,Week 16,n=0,1,1,1,0	-0.0030 (± 99999)			
Hematocrit,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Hematocrit,Week 36,n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameter -Erythrocytes Mean Corpuscular Volume for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameter - Erythrocytes Mean Corpuscular Volume for participants who received at least one dose of 100 mg open-label Sirukumab in
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End point description:

Blood samples were collected to analyze the hematology parameter Erythrocytes Mean Corpuscular Volume. Change from Baseline is presented for this parameter. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL sirukumab is presented.

End point type

Secondary

End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone	PartB:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Femtoliter				
arithmetic mean (standard deviation)				
Week 2,n=1,1,0,1,2	-2.0 (± 99999)	1.0 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Week 4,n=2,1,1,2,2	1.5 (± 0.71)	1.0 (± 99999)	1.0 (± 99999)	-1.5 (± 0.71)
Week 8,n=2,1,1,2,1	1.5 (± 2.12)	-1.0 (± 99999)	0.0 (± 99999)	-2.5 (± 0.71)
Week 12,n=2,0,1,1,0	2.5 (± 0.71)	99999 (± 99999)	0.0 (± 99999)	-6.0 (± 99999)
Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	-5.0 (± 99999)
Week 16,n=2,0,0,1,0	0.5 (± 0.71)	99999 (± 99999)	99999 (± 99999)	-4.0 (± 99999)
Week 24,n=2,0,0,0,0	1.5 (± 0.71)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 36,n=2,0,0,0,0	2.5 (± 2.12)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 38,n=1,0,0,0,0	0.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 40,n=1,0,0,0,0	-2.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Femtoliter				
arithmetic mean (standard deviation)				
Week 2,n=1,1,0,1,2	0.5 (± 3.54)			
Week 4,n=2,1,1,2,2	0.5 (± 2.12)			
Week 8,n=2,1,1,2,1	2.0 (± 2.83)			
Week 12,n=2,0,1,1,0	99999 (± 99999)			

Week 14,n=0,0,0,1,0	99999 (± 99999)			
Week 16,n=2,0,0,1,0	99999 (± 99999)			
Week 24,n=2,0,0,0,0	99999 (± 99999)			
Week 36,n=2,0,0,0,0	99999 (± 99999)			
Week 38,n=1,0,0,0,0	99999 (± 99999)			
Week 40,n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameter -Erythrocytes Mean Corpuscular Volume for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameter - Erythrocytes Mean Corpuscular Volume for participants who never received 100 mg open label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the hematology parameter Hematocrit. Change from Baseline is presented for this parameter. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 4,8,12,16,24 and 36

End point values	PartB:Placebo SC q2w + 12 month Prednisone	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Femtoliter				
arithmetic mean (standard deviation)				
Week 4,n=3,3,2,1,2	2.0 (± 1.41)	0.7 (± 1.15)	1.3 (± 1.53)	0.0 (± 0.00)
Week 8,n=2,1,2,0,2	1.5 (± 0.71)	-0.5 (± 0.71)	1.0 (± 99999)	0.0 (± 1.41)
Week 12,n=1,1,1,1,1	2.0 (± 99999)	0.0 (± 99999)	2.0 (± 99999)	-1.0 (± 99999)
Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	1.0 (± 99999)	0.0 (± 99999)
Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	3.0 (± 99999)	99999 (± 99999)
Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	4.0 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 6 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Femtoliter				
arithmetic mean (standard deviation)				
Week 4,n=3,3,2,1,2	-3.0 (± 99999)			
Week 8,n=2,1,2,0,2	99999 (± 99999)			
Week 12,n=1,1,1,1,1	1.0 (± 99999)			
Week 16,n=0,1,1,1,0	2.0 (± 99999)			
Week 24,n=0,1,0,0,0	99999 (± 99999)			
Week 36,n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameter-Erythrocytes Mean Corpuscular Hemoglobin for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameter-Erythrocytes Mean Corpuscular Hemoglobin for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the hematology parameter Erythrocytes Mean Corpuscular Hemoglobin. Change from Baseline is presented for this parameter. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL Sirukumab is presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone	PartB:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Picograms				
arithmetic mean (standard deviation)				

Week 2,n=1,1,0,1,2	-1.10 (± 99999)	0.20 (± 99999)	99999 (± 99999)	-0.20 (± 99999)
Week 4,n=2,1,1,2,2	0.30 (± 0.000)	0.60 (± 99999)	0.20 (± 99999)	-0.05 (± 0.354)
Week 8,n=2,1,1,2,2	0.30 (± 0.424)	1.30 (± 99999)	0.30 (± 99999)	-0.45 (± 0.919)
Week 12,n=2,1,1,1,0	0.25 (± 0.212)	99999 (± 99999)	0.30 (± 99999)	0.00 (± 99999)
Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	-0.90 (± 99999)
Week 16,n=2,0,0,1,0	0.00 (± 0.00)	99999 (± 99999)	99999 (± 99999)	-0.10 (± 99999)
Week 24,n=2,0,0,0,0	0.10 (± 0.141)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 36,n=2,0,0,0,0	0.25 (± 0.354)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 38,n=1,0,0,0,0	-0.40 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 40,n=1,0,0,0,0	0.40 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Picograms				
arithmetic mean (standard deviation)				
Week 2,n=1,1,0,1,2	0.60 (± 0.990)			
Week 4,n=2,1,1,2,2	1.00 (± 1.273)			
Week 8,n=2,1,1,2,2	0.70 (± 0.141)			
Week 12,n=2,1,1,1,0	99999 (± 99999)			
Week 14,n=0,0,0,1,0	99999 (± 99999)			
Week 16,n=2,0,0,1,0	99999 (± 99999)			
Week 24,n=2,0,0,0,0	99999 (± 99999)			
Week 36,n=2,0,0,0,0	99999 (± 99999)			
Week 38,n=1,0,0,0,0	99999 (± 99999)			
Week 40,n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameter-Erythrocytes Mean Corpuscular Hemoglobin for participants who never received 100 mg open

label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameter- Erythrocytes Mean Corpuscular Hemoglobin for participants who never received 100 mg open label Sirukumab in Part B
End point description: Blood samples were collected to analyze the hematology parameter Erythrocytes Mean Corpuscular Hemoglobin. Change from Baseline is presented for this parameter. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented.	
End point type	Secondary
End point timeframe: Baseline (Week 0) and Weeks 4,8,12,16,24 and 36	

End point values	PartB:Placebo SC q2w + 12 month Prednisone	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Picograms				
arithmetic mean (standard deviation)				
Week 4,n=3,3,2,1,2	0.00 (± 0.849)	-0.33 (± 0.757)	-0.47 (± 0.451)	-0.25 (± 0.354)
Week 8,n=2,1,2,0,2	1.10 (± 2.121)	-0.15 (± 0.354)	-0.60 (± 99999)	0.00 (± 1.273)
Week 12,n=1,1,1,1,1	1.80 (± 99999)	-0.10 (± 99999)	-0.50 (± 99999)	0.70 (± 99999)
Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-0.80 (± 99999)	-0.20 (± 99999)
Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.80 (± 99999)	99999 (± 99999)
Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.20 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 6 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Picograms				
arithmetic mean (standard deviation)				
Week 4,n=3,3,2,1,2	-1.00 (± 99999)			
Week 8,n=2,1,2,0,2	99999 (± 99999)			
Week 12,n=1,1,1,1,1	2.20 (± 99999)			
Week 16,n=0,1,1,1,0	1.30 (± 99999)			
Week 24,n=0,1,0,0,0	99999 (± 99999)			
Week 36,n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameter- Erythrocytes for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameter- Erythrocytes for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the hematology parameter Erythrocytes. Change from Baseline is presented for this parameter. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL Sirukumab is presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone	PartB:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Trillion cells per liter				
arithmetic mean (standard deviation)				
Week 2,n=1,1,0,1,2	0.00 (± 99999)	-0.10 (± 99999)	99999 (± 99999)	0.30 (± 99999)
Week 4,n=2,1,1,2,2	0.00 (± 0.000)	-0.10 (± 99999)	-0.30 (± 99999)	0.00 (± 0.283)
Week 8,n=2,1,1,2,2	0.10 (± 0.141)	0.00 (± 99999)	0.00 (± 99999)	0.05 (± 0.212)
Week 12,n=2,1,1,1,0	0.10 (± 0.141)	99999 (± 99999)	0.00 (± 99999)	-0.20 (± 99999)
Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.10 (± 99999)
Week 16,n=2,0,0,1,0	0.00 (± 0.00)	99999 (± 99999)	99999 (± 99999)	-0.20 (± 99999)
Week 24,n=2,0,0,0,0	0.00 (± 0.283)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 36,n=2,0,0,0,0	-0.05 (± 0.071)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 38,n=1,0,0,0,0	0.00 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 40,n=1,0,0,0,0	0.00 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Trillion cells per liter				
arithmetic mean (standard deviation)				
Week 2,n=1,1,0,1,2	0.25 (± 0.071)			
Week 4,n=2,1,1,2,2	0.10 (± 0.141)			
Week 8,n=2,1,1,2,2	0.15 (± 0.071)			
Week 12,n=2,1,1,1,0	99999 (± 99999)			
Week 14,n=0,0,0,1,0	99999 (± 99999)			
Week 16,n=2,0,0,1,0	99999 (± 99999)			
Week 24,n=2,0,0,0,0	99999 (± 99999)			
Week 36,n=2,0,0,0,0	99999 (± 99999)			
Week 38,n=1,0,0,0,0	99999 (± 99999)			
Week 40,n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in hematology parameter- Erythrocytes for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in hematology parameter- Erythrocytes for participants who never received 100 mg open label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the hematology parameter Erythrocytes. Change from Baseline is presented for this parameter. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 4,8,12,16,24 and 36

End point values	PartB:Placebo SC q2w + 12 month Prednisone	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Trillion cells per liter				
arithmetic mean (standard deviation)				
Week 4,n=3,3,2,1,2	-0.20 (± 0.000)	-0.03 (± 0.252)	-0.10 (± 0.173)	0.10 (± 0.283)
Week 8,n=2,1,2,0,2	-0.20 (± 0.000)	-0.15 (± 0.495)	0.00 (± 99999)	0.10 (± 0.283)
Week 12,n=1,1,1,1,1	-0.10 (± 99999)	-0.10 (± 99999)	0.10 (± 99999)	0.60 (± 99999)
Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	0.10 (± 99999)	0.70 (± 99999)
Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.00 (± 99999)	99999 (± 99999)
Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.10 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 6 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Trillion cells per liter				
arithmetic mean (standard deviation)				
Week 4,n=3,3,2,1,2	0.10 (± 99999)			
Week 8,n=2,1,2,0,2	99999 (± 99999)			
Week 12,n=1,1,1,1,1	0.00 (± 99999)			
Week 16,n=0,1,1,1,0	-0.10 (± 99999)			
Week 24,n=0,1,0,0,0	99999 (± 99999)			
Week 36,n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in clinical chemistry parameters- Calcium, Carbon Dioxide, Chloride, Glucose, Phosphate, Potassium, Sodium and Urea for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in clinical chemistry parameters- Calcium, Carbon Dioxide, Chloride, Glucose, Phosphate, Potassium, Sodium and Urea for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the chemistry parameters including Calcium, Carbon Dioxide, Chloride, Glucose, Phosphate, Potassium, Sodium and Urea. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL Sirukumab is presented.

End point type Secondary

End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone	PartB:Placebo SC q2w + 6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Calcium,Week 2,n=1,1,0,1,2	0.060 (± 99999)	0.000 (± 99999)	99999 (± 99999)	0.100 (± 99999)
Calcium,Week 4,n=2,1,1,2,2	0.070 (± 0.0707)	-0.100 (± 99999)	-0.080 (± 99999)	0.050 (± 0.1273)
Calcium,Week 8,n=2,1,1,2,1	0.120 (± 0.0283)	-0.140 (± 99999)	0.000 (± 99999)	-0.020 (± 0.0849)
Calcium,Week 12,n=2,1,1,1,0	0.110 (± 0.0990)	99999 (± 99999)	0.000 (± 99999)	-0.040 (± 99999)
Calcium,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.000 (± 99999)
Calcium,Week 16,n=2,0,0,1,0	0.000 (± 0.1131)	99999 (± 99999)	99999 (± 99999)	0.140 (± 99999)
Calcium,Week 24,n=2,0,0,0,0	0.040 (± 0.0566)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Calcium,Week 36,n=2,0,0,0,0	-0.050 (± 0.0707)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Calcium,Week 38,n=1,0,0,0,0	-0.020 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Calcium,Week 40,n=1,0,0,0,0	-0.020 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Carbon Dioxide,Week 2,n=1,1,0,1,2	3.0 (± 99999)	-5.0 (± 99999)	99999 (± 99999)	-2.0 (± 99999)
Carbon Dioxide,Week 4,n=2,1,1,2,2	3.5 (± 3.54)	-3.0 (± 99999)	2.0 (± 99999)	-1.5 (± 2.12)
Carbon Dioxide,Week 8,n=2,1,1,2,1	2.5 (± 2.12)	-4.0 (± 99999)	1.0 (± 99999)	-1.0 (± 0.00)
Carbon Dioxide,Week 12,n=2,1,1,1,0	3.5 (± 2.12)	99999 (± 99999)	2.0 (± 99999)	-3.0 (± 99999)
Carbon Dioxide,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1.0 (± 99999)
Carbon Dioxide,Week 16,n=2,0,0,1,0	0.5 (± 0.71)	99999 (± 99999)	99999 (± 99999)	-1.0 (± 99999)
Carbon Dioxide,Week 24,n=2,0,0,0,0	3.0 (± 0.00)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Carbon Dioxide,Week 36,n=2,0,0,0,0	1.5 (± 4.95)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Carbon Dioxide,Week 38,n=1,0,0,0,0	1.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Carbon Dioxide,Week 40,n=1,0,0,0,0	-2.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Chloride,Week 2,n=1,1,0,1,2	-1.0 (± 99999)	2.0 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Chloride,Week 4,n=2,1,1,2,2	-2.5 (± 0.71)	1.0 (± 99999)	6.0 (± 99999)	0.5 (± 2.12)
Chloride,Week 8,n=2,1,1,2,1	-3.0 (± 1.41)	0.0 (± 99999)	2.0 (± 99999)	1.0 (± 1.41)
Chloride,Week 12,n=2,1,1,1,0	-2.5 (± 0.71)	99999 (± 99999)	-1.0 (± 99999)	1.0 (± 99999)
Chloride,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1.0 (± 99999)
Chloride,Week 16,n=2,0,0,1,0	-1.0 (± 0.00)	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Chloride,Week 24,n=2,0,0,0,0	-2.0 (± 1.41)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Chloride,Week 36,n=2,0,0,0,0	0.5 (± 0.71)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Chloride,Week 38,n=1,0,0,0,0	-1.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Chloride,Week 40,n=1,0,0,0,0	0.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Glucose,Week 2,n=1,1,0,1,2	0.80 (± 99999)	0.20 (± 99999)	99999 (± 99999)	1.30 (± 99999)
Glucose,Week 4,n=2,1,1,2,2	0.95 (± 1.202)	0.40 (± 99999)	-0.70 (± 99999)	-0.05 (± 2.192)
Glucose,Week 8,n=2,1,1,2,1	0.70 (± 0.424)	0.00 (± 99999)	0.10 (± 99999)	0.30 (± 1.414)
Glucose,Week 12,n=2,1,1,1,0	0.60 (± 0.566)	0.00 (± 99999)	0.00 (± 99999)	-0.10 (± 99999)
Glucose,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	-0.10 (± 99999)
Glucose,Week 16,n=2,0,0,1,0	0.55 (± 0.071)	99999 (± 99999)	99999 (± 99999)	-0.20 (± 99999)
Glucose,Week 24,n=2,0,0,0,0	0.65 (± 0.354)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Glucose,Week 36,n=2,0,0,0,0	0.35 (± 0.071)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Glucose,Week 38,n=1,0,0,0,0	0.50 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Glucose,Week 40,n=1,0,0,0,0	3.60 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Phosphate,Week 2,n=1,1,0,1,2	0.050 (± 99999)	-0.100 (± 99999)	99999 (± 99999)	-0.300 (± 99999)
Phosphate,Week 4,n=2,1,1,2,2	-0.125 (± 0.1768)	-0.250 (± 99999)	0.000 (± 99999)	0.050 (± 0.2828)
Phosphate,Week 8,n=2,1,1,2,1	0.025 (± 0.1061)	-0.200 (± 99999)	0.150 (± 99999)	-0.075 (± 0.3182)
Phosphate,Week 12,n=2,1,1,1,0	-0.025 (± 0.1768)	99999 (± 99999)	0.050 (± 99999)	0.200 (± 99999)
Phosphate,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.250 (± 99999)
Phosphate,Week 16,n=2,0,0,1,0	-0.050 (± 0.0707)	99999 (± 99999)	99999 (± 99999)	0.300 (± 99999)
Phosphate,Week 24,n=2,0,0,0,0	0.050 (± 0.0000)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Phosphate,Week 36,n=2,0,0,0,0	-0.025 (± 0.0354)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Phosphate,Week 38,n=1,0,0,0,0	0.000 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Phosphate,Week 40,n=1,0,0,0,0	0.000 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Potassium,Week 2,n=1,1,0,1,2	0.10 (± 99999)	-0.20 (± 99999)	99999 (± 99999)	0.00 (± 99999)
Potassium,Week 4,n=2,1,1,2,2	0.20 (± 0.283)	-0.20 (± 99999)	0.20 (± 99999)	-0.30 (± 0.141)

Potassium,Week 8,n=2,1,1,2,1	0.10 (± 0.424)	0.00 (± 99999)	0.50 (± 99999)	-0.30 (± 0.424)
Potassium,Week 12,n=2,1,1,1,0	0.25 (± 0.636)	99999 (± 99999)	0.30 (± 99999)	0.10 (± 99999)
Potassium,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.00 (± 99999)
Potassium,Week 16,n=2,0,0,1,0	0.00 (± 0.141)	99999 (± 99999)	99999 (± 99999)	-0.10 (± 99999)
Potassium,Week 24,n=2,0,0,0,0	0.40 (± 0.283)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Potassium,Week 36,n=2,0,0,0,0	0.20 (± 0.424)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Potassium,Week 38,n=1,0,0,0,0	0.00 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Potassium,Week 40,n=1,0,0,0,0	-0.30 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Sodium,Week 2,n=1,1,0,1,2	0.0 (± 99999)	-2.0 (± 99999)	99999 (± 99999)	-2.0 (± 99999)
Sodium,Week 4,n=2,1,1,2,2	-0.5 (± 0.71)	-1.0 (± 99999)	3.0 (± 99999)	0.5 (± 4.95)
Sodium,Week 8,n=2,1,1,2,1	-2.0 (± 1.41)	-1.0 (± 99999)	0.0 (± 99999)	-0.5 (± 3.54)
Sodium,Week 12,n=2,1,1,1,0	-1.0 (± 1.41)	99999 (± 99999)	-2.0 (± 99999)	2.0 (± 99999)
Sodium,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	2.0 (± 99999)
Sodium,Week 16,n=2,0,0,1,0	-1.5 (± 0.71)	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Sodium,Week 24,n=2,0,0,0,0	-0.5 (± 0.71)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Sodium,Week 36,n=2,0,0,0,0	2.0 (± 0.00)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Sodium,Week 38,n=1,0,0,0,0	-1.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Sodium,Week 40,n=1,0,0,0,0	2.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Urea,Week 2,n=1,1,0,1,2	-1.00 (± 99999)	-2.50 (± 99999)	99999 (± 99999)	0.50 (± 99999)
Urea,Week 4,n=2,1,1,2,2	1.25 (± 0.354)	-1.00 (± 99999)	1.50 (± 99999)	1.50 (± 0.707)
Urea,Week 8,n=2,1,1,2,1	2.00 (± 2.121)	-2.00 (± 99999)	3.00 (± 99999)	-0.25 (± 0.354)
Urea,Week 12,n=2,1,1,1,0	-0.50 (± 2.121)	99999 (± 99999)	1.50 (± 99999)	0.00 (± 99999)
Urea,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1.00 (± 99999)
Urea,Week 16,n=2,0,0,1,0	1.25 (± 1.768)	99999 (± 99999)	99999 (± 99999)	1.50 (± 99999)
Urea,Week 24,n=2,0,0,0,0	0.00 (± 0.000)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Urea,Week 36,n=2,0,0,0,0	0.00 (± 0.707)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Urea,Week 38,n=1,0,0,0,0	1.50 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Urea,Week 40,n=1,0,0,0,0	1.50 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month Prednisone			
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Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Calcium,Week 2,n=1,1,0,1,2	0.040 (± 0.0000)			
Calcium,Week 4,n=2,1,1,2,2	0.000 (± 0.0566)			
Calcium,Week 8,n=2,1,1,2,1	0.020 (± 99999)			
Calcium,Week 12,n=2,1,1,1,0	99999 (± 99999)			
Calcium,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Calcium,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Calcium,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Calcium,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Calcium,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Calcium,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Carbon Dioxide,Week 2,n=1,1,0,1,2	-1.0 (± 0.00)			
Carbon Dioxide,Week 4,n=2,1,1,2,2	-3.5 (± 2.12)			
Carbon Dioxide,Week 8,n=2,1,1,2,1	-1.0 (± 99999)			
Carbon Dioxide,Week 12,n=2,1,1,1,0	99999 (± 99999)			
Carbon Dioxide,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Carbon Dioxide,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Carbon Dioxide,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Carbon Dioxide,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Carbon Dioxide,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Carbon Dioxide,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Chloride,Week 2,n=1,1,0,1,2	1.0 (± 1.41)			
Chloride,Week 4,n=2,1,1,2,2	1.5 (± 0.71)			
Chloride,Week 8,n=2,1,1,2,1	3.0 (± 99999)			
Chloride,Week 12,n=2,1,1,1,0	99999 (± 99999)			
Chloride,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Chloride,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Chloride,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Chloride,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Chloride,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Chloride,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Glucose,Week 2,n=1,1,0,1,2	1.25 (± 1.202)			

Glucose,Week 4,n=2,1,1,2,2	-0.05 (± 0.212)			
Glucose,Week 8,n=2,1,1,2,1	0.20 (± 99999)			
Glucose,Week 12,n=2,1,1,1,0	99999 (± 99999)			
Glucose,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Glucose,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Glucose,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Glucose,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Glucose,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Glucose,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Phosphate,Week 2,n=1,1,0,1,2	0.000 (± 0.0707)			
Phosphate,Week 4,n=2,1,1,2,2	-0.050 (± 0.1414)			
Phosphate,Week 8,n=2,1,1,2,1	-0.050 (± 99999)			
Phosphate,Week 12,n=2,1,1,1,0	99999 (± 99999)			
Phosphate,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Phosphate,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Phosphate,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Phosphate,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Phosphate,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Phosphate,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Potassium,Week 2,n=1,1,0,1,2	0.10 (± 0.283)			
Potassium,Week 4,n=2,1,1,2,2	0.00 (± 0.141)			
Potassium,Week 8,n=2,1,1,2,1	0.10 (± 99999)			
Potassium,Week 12,n=2,1,1,1,0	99999 (± 99999)			
Potassium,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Potassium,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Potassium,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Potassium,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Potassium,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Potassium,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Sodium,Week 2,n=1,1,0,1,2	1.0 (± 0.00)			
Sodium,Week 4,n=2,1,1,2,2	0.5 (± 0.71)			
Sodium,Week 8,n=2,1,1,2,1	2.0 (± 99999)			
Sodium,Week 12,n=2,1,1,1,0	99999 (± 99999)			
Sodium,Week 14,n=0,0,0,1,0	99999 (± 99999)			

Sodium,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Sodium,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Sodium,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Sodium,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Sodium,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Urea,Week 2,n=1,1,0,1,2	0.75 (± 0.354)			
Urea,Week 4,n=2,1,1,2,2	0.25 (± 0.354)			
Urea,Week 8,n=2,1,1,2,1	0.50 (± 99999)			
Urea,Week 12,n=2,1,1,1,0	99999 (± 99999)			
Urea,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Urea,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Urea,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Urea,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Urea,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Urea,Week 40,n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in clinical chemistry parameters- Calcium, Carbon Dioxide, Chloride, Glucose, Phosphate, Potassium, Sodium and Urea for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in clinical chemistry parameters- Calcium, Carbon Dioxide, Chloride, Glucose, Phosphate, Potassium, Sodium and Urea for participants who never received 100 mg open label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the chemistry parameters including Calcium, Carbon Dioxide, Chloride, Glucose, Phosphate, Potassium, Sodium and Urea. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 4,8,12,16,24 and 36

End point values	PartB:Placebo SC q2w + 12 month Prednisone	PartB:SIR 100 mg SC q2w+6 month Prednisone	PartB:SIR 100 mg SC q2w+3 month Prednisone	PartB:SIR 50 mg SC q4w+6 month Prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Calcium,Week 4,n=3,3,2,1,2	-0.040 (± 0.0566)	0.067 (± 0.0643)	-0.093 (± 0.0462)	0.060 (± 0.1414)
Calcium,Week 8,n=2,1,2,0,2	0.020 (± 0.0000)	0.010 (± 0.0707)	-0.060 (± 99999)	0.050 (± 0.0707)
Calcium,Week 12,n=1,1,1,1,1	0.000 (± 99999)	0.020 (± 99999)	0.040 (± 99999)	0.160 (± 99999)
Calcium,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	0.040 (± 99999)	0.180 (± 99999)
Calcium,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.040 (± 99999)	99999 (± 99999)
Calcium,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.020 (± 99999)	99999 (± 99999)
Carbon Dioxide,Week 4,n=3,3,2,1,2	-3.0 (± 0.00)	0.0 (± 2.00)	-2.7 (± 1.15)	0.0 (± 2.83)
Carbon Dioxide,Week 8,n=2,1,2,0,2	-1.5 (± 0.71)	-0.5 (± 0.71)	-4.0 (± 99999)	0.5 (± 3.54)
Carbon Dioxide,Week 12,n=1,1,1,1,1	-3.0 (± 99999)	1.0 (± 99999)	-2.0 (± 99999)	0.0 (± 99999)
Carbon Dioxide,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)	1.0 (± 99999)
Carbon Dioxide,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	1.0 (± 99999)	99999 (± 99999)
Carbon Dioxide,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-2.0 (± 99999)	99999 (± 99999)
Chloride,Week 4,n=3,3,2,1,2	0.5 (± 0.71)	0.7 (± 1.15)	0.3 (± 3.06)	-2.5 (± 4.95)
Chloride,Week 8,n=2,1,2,0,2	0.5 (± 2.12)	-2.0 (± 0.00)	-1.0 (± 99999)	-2.5 (± 2.12)
Chloride,Week 12,n=1,1,1,1,1	-2.0 (± 99999)	-2.0 (± 99999)	0.0 (± 99999)	-4.0 (± 99999)
Chloride,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	1.0 (± 99999)	-5.0 (± 99999)
Chloride,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	1.0 (± 99999)	99999 (± 99999)
Chloride,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)	99999 (± 99999)
Glucose,Week 4,n=3,3,2,1,2	-0.40 (± 0.707)	-0.10 (± 0.608)	0.33 (± 1.115)	-0.80 (± 0.849)
Glucose,Week 8,n=2,1,2,0,2	0.55 (± 0.354)	0.15 (± 1.061)	0.60 (± 99999)	-0.85 (± 0.071)
Glucose,Week 12,n=1,1,1,1,1	0.20 (± 99999)	0.00 (± 99999)	2.80 (± 99999)	0.30 (± 99999)
Glucose,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	1.40 (± 99999)	0.30 (± 99999)
Glucose,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	1.10 (± 99999)	99999 (± 99999)
Glucose,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	2.10 (± 99999)	99999 (± 99999)
Phosphate,Week 4,n=3,3,2,1,2	-0.025 (± 0.1061)	0.050 (± 0.2646)	-0.033 (± 0.1155)	-0.125 (± 0.1768)
Phosphate,Week 8,n=2,1,2,0,2	-0.075 (± 0.0354)	0.150 (± 0.1414)	-0.100 (± 99999)	-0.250 (± 0.2121)
Phosphate,Week 12,n=1,1,1,1,1	-0.100 (± 99999)	0.050 (± 99999)	-0.250 (± 99999)	0.000 (± 99999)
Phosphate,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	0.100 (± 99999)	0.000 (± 99999)
Phosphate,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.050 (± 99999)	99999 (± 99999)

Phosphate,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.150 (± 99999)	99999 (± 99999)
Potassium,Week 4,n=3,3,2,1,2	-0.10 (± 0.141)	-0.27 (± 0.289)	0.03 (± 0.321)	0.10 (± 0.141)
Potassium,Week 8,n=2,1,2,0,2	-0.10 (± 0.283)	-0.25 (± 0.212)	-0.30 (± 99999)	0.00 (± 0.424)
Potassium,Week 12,n=1,1,1,1,1	-0.40 (± 99999)	-0.20 (± 99999)	-0.20 (± 99999)	0.40 (± 99999)
Potassium,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-0.10 (± 99999)	-0.10 (± 99999)
Potassium,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.10 (± 99999)	99999 (± 99999)
Potassium,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.20 (± 99999)	99999 (± 99999)
Sodium,Week 4,n=3,3,2,1,2	-1.0 (± 1.41)	0.3 (± 1.53)	-1.0 (± 2.65)	-3.0 (± 2.83)
Sodium,Week 8,n=2,1,2,0,2	-1.0 (± 1.41)	-2.5 (± 0.71)	2.0 (± 99999)	-3.5 (± 3.54)
Sodium,Week 12,n=1,1,1,1,1	-4.0 (± 99999)	-2.0 (± 99999)	1.0 (± 99999)	-4.0 (± 99999)
Sodium,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)	-4.0 (± 99999)
Sodium,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	3.0 (± 99999)	99999 (± 99999)
Sodium,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	1.0 (± 99999)	99999 (± 99999)
Urea,Week 4,n=3,3,2,1,2	-0.25 (± 1.061)	-0.83 (± 0.577)	-0.50 (± 1.323)	-0.50 (± 0.707)
Urea,Week 8,n=2,1,2,0,2	0.50 (± 0.707)	-0.50 (± 0.707)	0.00 (± 99999)	-0.75 (± 0.354)
Urea,Week 12,n=1,1,1,1,1	-2.50 (± 99999)	-0.50 (± 99999)	-1.50 (± 99999)	0.00 (± 99999)
Urea,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	0.00 (± 99999)	-0.50 (± 99999)
Urea,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-0.50 (± 99999)	99999 (± 99999)
Urea,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-1.00 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 6 month Prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Calcium,Week 4,n=3,3,2,1,2	0.120 (± 99999)			
Calcium,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Calcium,Week 12,n=1,1,1,1,1	0.000 (± 99999)			
Calcium,Week 16,n=0,1,1,1,0	0.060 (± 99999)			
Calcium,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Calcium,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Carbon Dioxide,Week 4,n=3,3,2,1,2	-1.0 (± 99999)			

Carbon Dioxide,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Carbon Dioxide,Week 12,n=1,1,1,1,1	0.0 (± 99999)			
Carbon Dioxide,Week 16,n=0,1,1,1,0	0.0 (± 99999)			
Carbon Dioxide,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Carbon Dioxide,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Chloride,Week 4,n=3,3,2,1,2	-4.0 (± 99999)			
Chloride,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Chloride,Week 12,n=1,1,1,1,1	-2.0 (± 99999)			
Chloride,Week 16,n=0,1,1,1,0	-1.0 (± 99999)			
Chloride,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Chloride,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Glucose,Week 4,n=3,3,2,1,2	0.70 (± 99999)			
Glucose,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Glucose,Week 12,n=1,1,1,1,1	-0.50 (± 99999)			
Glucose,Week 16,n=0,1,1,1,0	2.10 (± 99999)			
Glucose,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Glucose,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Phosphate,Week 4,n=3,3,2,1,2	0.050 (± 99999)			
Phosphate,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Phosphate,Week 12,n=1,1,1,1,1	0.250 (± 99999)			
Phosphate,Week 16,n=0,1,1,1,0	0.000 (± 99999)			
Phosphate,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Phosphate,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Potassium,Week 4,n=3,3,2,1,2	0.40 (± 99999)			
Potassium,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Potassium,Week 12,n=1,1,1,1,1	0.00 (± 99999)			
Potassium,Week 16,n=0,1,1,1,0	-0.20 (± 99999)			
Potassium,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Potassium,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Sodium,Week 4,n=3,3,2,1,2	-3.0 (± 99999)			
Sodium,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Sodium,Week 12,n=1,1,1,1,1	0.0 (± 99999)			
Sodium,Week 16,n=0,1,1,1,0	0.0 (± 99999)			
Sodium,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Sodium,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Urea,Week 4,n=3,3,2,1,2	0.00 (± 99999)			

Urea,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Urea,Week 12,n=1,1,1,1,1	-1.00 (± 99999)			
Urea,Week 16,n=0,1,1,1,0	0.50 (± 99999)			
Urea,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Urea,Week 36,n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in clinical chemistry parameters: Albumin and Protein for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in clinical chemistry parameters: Albumin and Protein for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the chemistry parameters including Albumin and Protein. Change from Baseline is presented for these parameters. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL sirukumab is presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Grams per liter				
arithmetic mean (standard deviation)				
Albumin,Week 2,n=1,1,0,1,2	-1.0 (± 99999)	99999 (± 99999)	-1.0 (± 99999)	5.0 (± 99999)
Albumin,Week 4,n=2,1,1,2,2	0.0 (± 1.41)	-1.0 (± 99999)	0.0 (± 99999)	0.0 (± 2.83)
Albumin,Week 8,n=2,1,1,2,1	1.0 (± 2.83)	0.0 (± 99999)	0.0 (± 99999)	-2.0 (± 2.83)
Albumin,Week 12,n=2,0,1,1,0	1.0 (± 0.00)	1.0 (± 99999)	99999 (± 99999)	-4.0 (± 99999)
Albumin,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Albumin,Week 16,n=2,0,0,1,0	-0.5 (± 2.12)	99999 (± 99999)	99999 (± 99999)	2.0 (± 99999)
Albumin,Week 24,n=2,0,0,0,0	-0.5 (± 3.54)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Albumin,Week 36,n=2,0,0,0,0	-1.0 (± 2.83)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Albumin,Week 38,n=1,0,0,0,0	-2.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Albumin,Week 40,n=1,0,0,0,0	-2.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Protein,Week 2,n=1,1,0,1,2	0.0 (± 99999)	99999 (± 99999)	-1.0 (± 99999)	8.0 (± 99999)
Protein,Week 4,n=2,1,1,2,2	1.0 (± 1.41)	-2.0 (± 99999)	0.0 (± 99999)	-0.5 (± 4.95)
Protein,Week 8,n=2,1,1,2,1	3.0 (± 1.41)	2.0 (± 99999)	0.0 (± 99999)	-2.5 (± 4.95)
Protein,Week 12,n=2,0,1,1,0	2.5 (± 2.12)	2.0 (± 99999)	99999 (± 99999)	-4.0 (± 99999)
Protein,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	-5.0 (± 99999)
Protein,Week 16,n=2,0,0,1,0	1.0 (± 1.41)	99999 (± 99999)	99999 (± 99999)	-2.0 (± 99999)
Protein,Week 24,n=2,0,0,0,0	0.5 (± 3.54)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Protein,Week 36,n=2,0,0,0,0	1.5 (± 0.71)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Protein,Week 38,n=1,0,0,0,0	1.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Protein,Week 40,n=1,0,0,0,0	0.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Grams per liter				
arithmetic mean (standard deviation)				
Albumin,Week 2,n=1,1,0,1,2	3.5 (± 0.71)			
Albumin,Week 4,n=2,1,1,2,2	3.0 (± 1.41)			
Albumin,Week 8,n=2,1,1,2,1	2.0 (± 99999)			
Albumin,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Albumin,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Albumin,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Albumin,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Albumin,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Albumin,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Albumin,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Protein,Week 2,n=1,1,0,1,2	1.5 (± 2.12)			
Protein,Week 4,n=2,1,1,2,2	-0.5 (± 2.12)			
Protein,Week 8,n=2,1,1,2,1	0.0 (± 99999)			
Protein,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Protein,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Protein,Week 16,n=2,0,0,1,0	99999 (± 99999)			

Protein,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Protein,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Protein,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Protein,Week 40,n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in clinical chemistry parameters: Albumin and Protein for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in clinical chemistry parameters: Albumin and Protein for participants who never received 100 mg open label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the chemistry parameters including Albumin and Protein. Change from Baseline is presented for these parameters. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 4,8,12,16,24 and 36

End point values	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Grams per liter				
arithmetic mean (standard deviation)				
Albumin,Week 4,n=3,3,2,1,2	-2.5 (± 0.71)	-0.3 (± 1.53)	-1.3 (± 0.58)	1.0 (± 1.41)
Albumin,Week 8,n=2,1,2,0,2	-1.5 (± 0.71)	1.5 (± 2.12)	-2.0 (± 99999)	1.0 (± 2.83)
Albumin,Week 12,n=1,1,1,1,1	0.0 (± 99999)	3.0 (± 99999)	-1.0 (± 99999)	5.0 (± 99999)
Albumin,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-2.0 (± 99999)	5.0 (± 99999)
Albumin,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-1.0 (± 99999)	99999 (± 99999)
Albumin,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-2.0 (± 99999)	99999 (± 99999)
Protein,Week 4,n=3,3,2,1,2	-5.0 (± 2.83)	-0.3 (± 3.21)	-2.7 (± 1.53)	1.0 (± 5.66)
Protein,Week 8,n=2,1,2,0,2	-1.5 (± 3.54)	1.5 (± 3.54)	-2.0 (± 99999)	2.5 (± 4.95)
Protein,Week 12,n=1,1,1,1,1	2.0 (± 99999)	3.0 (± 99999)	-2.0 (± 99999)	9.0 (± 99999)
Protein,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-2.0 (± 99999)	12.0 (± 99999)

Protein,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-1.0 (± 99999)	99999 (± 99999)
Protein,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-2.0 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Grams per liter				
arithmetic mean (standard deviation)				
Albumin,Week 4,n=3,3,2,1,2	0.0 (± 99999)			
Albumin,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Albumin,Week 12,n=1,1,1,1,1	3.0 (± 99999)			
Albumin,Week 16,n=0,1,1,1,0	0.0 (± 99999)			
Albumin,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Albumin,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Protein,Week 4,n=3,3,2,1,2	0.0 (± 99999)			
Protein,Week 8,n=2,1,2,0,2	99999 (± 99999)			
Protein,Week 12,n=1,1,1,1,1	1.0 (± 99999)			
Protein,Week 16,n=0,1,1,1,0	-1.0 (± 99999)			
Protein,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Protein,Week 36,n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in clinical chemistry parameters: ALT, ALP and AST for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in clinical chemistry parameters: ALT, ALP and AST for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the chemistry parameters including ALT,ALP and AST. Change from Baseline is presented for these parameters. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL sirukumab is presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT,Week 2,n=1,1,0,1,2	1.0 (± 99999)	99999 (± 99999)	4.0 (± 99999)	3.0 (± 99999)
ALT,Week 4,n=2,1,1,2,2	-1.5 (± 3.54)	0.0 (± 99999)	4.0 (± 99999)	4.0 (± 9.90)
ALT,Week 8,n=2,1,1,2,2	2.5 (± 4.95)	1.0 (± 99999)	2.0 (± 99999)	4.5 (± 7.78)
ALT,Week 12,n=2,0,1,1,0	-3.0 (± 7.07)	4.0 (± 99999)	99999 (± 99999)	-3.0 (± 99999)
ALT,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	2.0 (± 99999)
ALT,Week 16,n=2,0,0,1,0	-1.0 (± 2.83)	99999 (± 99999)	99999 (± 99999)	2.0 (± 99999)
ALT,Week 24,n=2,0,0,0,0	-2.5 (± 6.36)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
ALT,Week 36,n=2,0,0,0,0	-4.5 (± 9.19)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
ALT,Week 38,n=1,0,0,0,0	-9.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
ALT,Week 40,n=1,0,0,0,0	-9.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
ALP,Week 2,n=1,1,0,1,2	7.0 (± 99999)	99999 (± 99999)	-2.0 (± 99999)	-17.0 (± 99999)
ALP,Week 4,n=2,1,1,2,2	5.5 (± 0.71)	-4.0 (± 99999)	-9.0 (± 99999)	-9.0 (± 14.14)
ALP,Week 8,n=2,1,1,2,2	7.0 (± 1.41)	-3.0 (± 99999)	-16.0 (± 99999)	-4.5 (± 26.16)
ALP,Week 12,n=2,0,1,1,0	5.0 (± 1.41)	2.0 (± 99999)	99999 (± 99999)	8.0 (± 99999)
ALP,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	-15.0 (± 99999)
ALP,Week 16,n=2,0,0,1,0	-0.5 (± 0.71)	99999 (± 99999)	99999 (± 99999)	-9.0 (± 99999)
ALP,Week 24,n=2,0,0,0,0	2.5 (± 2.12)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
ALP,Week 36,n=2,0,0,0,0	2.0 (± 5.66)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
ALP,Week 38,n=1,0,0,0,0	7.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
ALP,Week 40,n=1,0,0,0,0	18.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AST,Week 2,n=1,1,0,1,2	0.0 (± 99999)	99999 (± 99999)	0.0 (± 99999)	3.0 (± 99999)
AST,Week 4,n=2,1,1,2,2	-4.5 (± 0.71)	0.0 (± 99999)	0.0 (± 99999)	-0.5 (± 3.54)
AST,Week 8,n=2,1,1,2,2	1.5 (± 0.71)	-3.0 (± 99999)	-2.0 (± 99999)	2.0 (± 4.24)
AST,Week 12,n=2,0,1,1,0	-4.0 (± 1.41)	-1.0 (± 99999)	99999 (± 99999)	-2.0 (± 99999)
AST,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)
AST,Week 16,n=2,0,0,1,0	-3.0 (± 2.83)	99999 (± 99999)	99999 (± 99999)	1.0 (± 99999)

AST,Week 24,n=2,0,0,0,0	-3.5 (± 2.12)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AST,Week 36,n=2,0,0,0,0	-4.5 (± 4.95)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AST,Week 38,n=1,0,0,0,0	-7.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AST,Week 40,n=1,0,0,0,0	-7.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT,Week 2,n=1,1,0,1,2	72.5 (± 101.12)			
ALT,Week 4,n=2,1,1,2,2	51.5 (± 64.35)			
ALT,Week 8,n=2,1,1,2,2	31.5 (± 24.75)			
ALT,Week 12,n=2,0,1,1,0	99999 (± 99999)			
ALT,Week 14,n=0,0,0,1,0	99999 (± 99999)			
ALT,Week 16,n=2,0,0,1,0	99999 (± 99999)			
ALT,Week 24,n=2,0,0,0,0	99999 (± 99999)			
ALT,Week 36,n=2,0,0,0,0	99999 (± 99999)			
ALT,Week 38,n=1,0,0,0,0	99999 (± 99999)			
ALT,Week 40,n=1,0,0,0,0	99999 (± 99999)			
ALP,Week 2,n=1,1,0,1,2	-5.0 (± 5.66)			
ALP,Week 4,n=2,1,1,2,2	-7.0 (± 5.66)			
ALP,Week 8,n=2,1,1,2,2	-12.0 (± 5.66)			
ALP,Week 12,n=2,0,1,1,0	99999 (± 99999)			
ALP,Week 14,n=0,0,0,1,0	99999 (± 99999)			
ALP,Week 16,n=2,0,0,1,0	99999 (± 99999)			
ALP,Week 24,n=2,0,0,0,0	99999 (± 99999)			
ALP,Week 36,n=2,0,0,0,0	99999 (± 99999)			
ALP,Week 38,n=1,0,0,0,0	99999 (± 99999)			
ALP,Week 40,n=1,0,0,0,0	99999 (± 99999)			
AST,Week 2,n=1,1,0,1,2	44.5 (± 57.28)			
AST,Week 4,n=2,1,1,2,2	23.0 (± 25.46)			
AST,Week 8,n=2,1,1,2,2	14.0 (± 5.66)			
AST,Week 12,n=2,0,1,1,0	99999 (± 99999)			

AST,Week 14,n=0,0,0,1,0	99999 (± 99999)			
AST,Week 16,n=2,0,0,1,0	99999 (± 99999)			
AST,Week 24,n=2,0,0,0,0	99999 (± 99999)			
AST,Week 36,n=2,0,0,0,0	99999 (± 99999)			
AST,Week 38,n=1,0,0,0,0	99999 (± 99999)			
AST,Week 40,n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in clinical chemistry parameters: ALT, ALP and AST for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in clinical chemistry parameters: ALT, ALP and AST for participants who never received 100 mg open label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the chemistry parameters including ALT,ALP and AST. Change from Baseline is presented for these parameters. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 4,8,12,16,24 and 36

End point values	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT,Week 4,n=3,3,2,1,2	1.0 (± 0.00)	2.3 (± 1.15)	2.7 (± 7.23)	-8.0 (± 4.24)
ALT,Week 8,n=2,1,2,0,2	-1.5 (± 3.54)	9.0 (± 7.07)	13.0 (± 99999)	-9.5 (± 9.19)
ALT,Week 12,n=1,1,1,1,1	2.0 (± 99999)	3.0 (± 99999)	8.0 (± 99999)	-4.0 (± 99999)
ALT,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-5.0 (± 99999)	-6.0 (± 99999)
ALT,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)	99999 (± 99999)
ALT,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-4.0 (± 99999)	99999 (± 99999)
ALP,Week 4,n=3,3,2,1,2	0.0 (± 14.14)	-0.7 (± 3.79)	0.0 (± 4.36)	0.5 (± 3.54)
ALP,Week 8,n=2,1,2,0,2	-3.0 (± 0.00)	1.5 (± 2.12)	-1.0 (± 99999)	-1.0 (± 4.24)

ALP,Week 12,n=1,1,1,1,1	-10.0 (± 99999)	-1.0 (± 99999)	0.0 (± 99999)	17.0 (± 99999)
ALP,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	4.0 (± 99999)	3.0 (± 99999)
ALP,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	2.0 (± 99999)	99999 (± 99999)
ALP,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	4.0 (± 99999)	99999 (± 99999)
AST,Week 4,n=3,3,2,1,2	-1.5 (± 3.54)	0.7 (± 1.53)	2.0 (± 3.00)	-5.0 (± 1.41)
AST,Week 8,n=2,1,2,0,2	0.0 (± 5.66)	10.5 (± 9.19)	7.0 (± 99999)	-6.0 (± 2.83)
AST,Week 12,n=1,1,1,1,1	2.0 (± 99999)	1.0 (± 99999)	-1.0 (± 99999)	2.0 (± 99999)
AST,Week 16,n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	-4.0 (± 99999)	0.0 (± 99999)
AST,Week 24,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-1.0 (± 99999)	99999 (± 99999)
AST,Week 36,n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	-3.0 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: International units per liter				
arithmetic mean (standard deviation)				
ALT,Week 4,n=3,3,2,1,2	103.0 (± 99999)			
ALT,Week 8,n=2,1,2,0,2	99999 (± 99999)			
ALT,Week 12,n=1,1,1,1,1	0.0 (± 99999)			
ALT,Week 16,n=0,1,1,1,0	1.0 (± 99999)			
ALT,Week 24,n=0,1,0,0,0	99999 (± 99999)			
ALT,Week 36,n=0,1,0,0,0	99999 (± 99999)			
ALP,Week 4,n=3,3,2,1,2	81.0 (± 99999)			
ALP,Week 8,n=2,1,2,0,2	99999 (± 99999)			
ALP,Week 12,n=1,1,1,1,1	-11.0 (± 99999)			
ALP,Week 16,n=0,1,1,1,0	-10.0 (± 99999)			
ALP,Week 24,n=0,1,0,0,0	99999 (± 99999)			
ALP,Week 36,n=0,1,0,0,0	99999 (± 99999)			
AST,Week 4,n=3,3,2,1,2	24.0 (± 99999)			
AST,Week 8,n=2,1,2,0,2	99999 (± 99999)			
AST,Week 12,n=1,1,1,1,1	0.0 (± 99999)			
AST,Week 16,n=0,1,1,1,0	2.0 (± 99999)			
AST,Week 24,n=0,1,0,0,0	99999 (± 99999)			
AST,Week 36,n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in clinical chemistry parameters: Bilirubin, Creatinine, Direct Bilirubin and Indirect Bilirubin for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Change from Baseline in clinical chemistry parameters: Bilirubin, Creatinine, Direct Bilirubin and Indirect Bilirubin for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
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End point description:

Blood samples were collected to analyze the chemistry parameters including Albumin and Protein. Change from Baseline is presented for these parameters. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who received at least one dose of 100 mg OL sirukumab is presented.

End point type	Secondary
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End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin,Week 2,n=1,1,0,1,2	0.0 (± 99999)	99999 (± 99999)	0.0 (± 99999)	2.0 (± 99999)
Bilirubin,Week 4,n=2,1,1,2,2	5.0 (± 1.41)	0.0 (± 99999)	-2.0 (± 99999)	1.0 (± 1.41)
Bilirubin,Week 8,n=2,1,1,2,2	-1.0 (± 4.24)	2.0 (± 99999)	0.0 (± 99999)	1.0 (± 4.24)
Bilirubin,Week 12,n=2,0,1,1,0	0.0 (± 8.49)	0.0 (± 99999)	99999 (± 99999)	-2.0 (± 99999)
Bilirubin,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Bilirubin,Week 16,n=2,0,0,1,0	5.0 (± 4.24)	99999 (± 99999)	99999 (± 99999)	2.0 (± 99999)
Bilirubin,Week 24,n=2,0,0,0,0	-2.0 (± 5.66)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Bilirubin,Week 36,n=2,0,0,0,0	1.0 (± 7.07)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Bilirubin,Week 38,n=1,0,0,0,0	0.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Bilirubin,Week 40,n=1,0,0,0,0	2.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Direct Bilirubin,Week 2,n=1,1,0,1,2	0.0 (± 99999)	99999 (± 99999)	0.0 (± 99999)	2.0 (± 99999)
Direct Bilirubin,Week 4,n=2,1,1,2,2	1.0 (± 1.41)	0.0 (± 99999)	0.0 (± 99999)	1.0 (± 1.41)
Direct Bilirubin,Week 8,n=2,1,1,2,1	0.0 (± 2.83)	0.0 (± 99999)	0.0 (± 99999)	1.0 (± 1.41)
Direct Bilirubin,Week 12,n=2,0,1,1,0	0.0 (± 2.83)	0.0 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Direct Bilirubin,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Direct Bilirubin,Week 16,n=2,0,0,1,0	1.0 (± 1.41)	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Direct Bilirubin,Week 24,n=2,0,0,0,0	0.0 (± 0.00)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Direct Bilirubin,Week 36,n=2,0,0,0,0	-1.0 (± 1.41)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Direct Bilirubin,Week 38,n=1,0,0,0,0	0.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Direct Bilirubin,Week 40,n=1,0,0,0,0	0.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Indirect Bilirubin,Week 2,n=1,1,0,1,2	0.0 (± 99999)	99999 (± 99999)	0.0 (± 99999)	0.0 (± 99999)
Indirect Bilirubin,Week 4,n=2,1,1,2,2	4.0 (± 0.00)	0.0 (± 99999)	-2.0 (± 99999)	0.0 (± 0.00)
Indirect Bilirubin,Week 8,n=2,1,1,2,1	-1.0 (± 1.41)	2.0 (± 99999)	0.0 (± 99999)	0.0 (± 2.83)
Indirect Bilirubin,Week 12,n=2,0,1,1,0	0.0 (± 5.66)	0.0 (± 99999)	99999 (± 99999)	-2.0 (± 99999)
Indirect Bilirubin,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.0 (± 99999)
Indirect Bilirubin,Week 16,n=2,0,0,1,0	4.0 (± 5.66)	99999 (± 99999)	99999 (± 99999)	2.0 (± 99999)
Indirect Bilirubin,Week 24,n=2,0,0,0,0	-2.0 (± 5.66)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Indirect Bilirubin,Week 36,n=2,0,0,0,0	2.0 (± 8.49)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Indirect Bilirubin,Week 38,n=1,0,0,0,0	0.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Indirect Bilirubin,Week 40,n=1,0,0,0,0	2.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Creatinine,Week 2,n=1,1,0,1,2	-3.50 (± 99999)	99999 (± 99999)	-6.20 (± 99999)	1.80 (± 99999)
Creatinine,Week 4,n=2,1,1,2,2	-11.05 (± 9.405)	2.70 (± 99999)	-12.40 (± 99999)	-1.30 (± 0.566)
Creatinine,Week 8,n=2,1,1,2,1	-8.40 (± 6.930)	9.70 (± 99999)	-8.00 (± 99999)	0.45 (± 5.728)
Creatinine,Week 12,n=2,0,1,1,0	-11.90 (± 11.879)	4.40 (± 99999)	99999 (± 99999)	-0.90 (± 99999)
Creatinine,Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.80 (± 99999)
Creatinine,Week 16,n=2,0,0,1,0	-12.80 (± 5.657)	99999 (± 99999)	99999 (± 99999)	4.40 (± 99999)
Creatinine,Week 24,n=2,0,0,0,0	-9.75 (± 12.516)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Creatinine,Week 36,n=2,0,0,0,0	-15.05 (± 9.970)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Creatinine,Week 38,n=1,0,0,0,0	-19.40 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Creatinine,Week 40,n=1,0,0,0,0	-20.30 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin,Week 2,n=1,1,0,1,2	-1.0 (± 1.41)			
Bilirubin,Week 4,n=2,1,1,2,2	1.0 (± 1.41)			
Bilirubin,Week 8,n=2,1,1,2,2	2.0 (± 0.00)			
Bilirubin,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Bilirubin,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Bilirubin,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Bilirubin,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Bilirubin,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Bilirubin,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Bilirubin,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Direct Bilirubin,Week 2,n=1,1,0,1,2	0.0 (± 0.00)			
Direct Bilirubin,Week 4,n=2,1,1,2,2	0.0 (± 0.00)			
Direct Bilirubin,Week 8,n=2,1,1,2,1	0.0 (± 99999)			
Direct Bilirubin,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Direct Bilirubin,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Direct Bilirubin,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Direct Bilirubin,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Direct Bilirubin,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Direct Bilirubin,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Direct Bilirubin,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Indirect Bilirubin,Week 2,n=1,1,0,1,2	-1.0 (± 1.41)			
Indirect Bilirubin,Week 4,n=2,1,1,2,2	1.0 (± 1.41)			
Indirect Bilirubin,Week 8,n=2,1,1,2,1	2.0 (± 99999)			
Indirect Bilirubin,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Indirect Bilirubin,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Indirect Bilirubin,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Indirect Bilirubin,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Indirect Bilirubin,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Indirect Bilirubin,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Indirect Bilirubin,Week 40,n=1,0,0,0,0	99999 (± 99999)			
Creatinine,Week 2,n=1,1,0,1,2	3.10 (± 1.838)			

Creatinine,Week 4,n=2,1,1,2,2	2.20 (± 4.384)			
Creatinine,Week 8,n=2,1,1,2,1	0.00 (± 99999)			
Creatinine,Week 12,n=2,0,1,1,0	99999 (± 99999)			
Creatinine,Week 14,n=0,0,0,1,0	99999 (± 99999)			
Creatinine,Week 16,n=2,0,0,1,0	99999 (± 99999)			
Creatinine,Week 24,n=2,0,0,0,0	99999 (± 99999)			
Creatinine,Week 36,n=2,0,0,0,0	99999 (± 99999)			
Creatinine,Week 38,n=1,0,0,0,0	99999 (± 99999)			
Creatinine,Week 40,n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in clinical chemistry parameters: Bilirubin, Creatinine, Direct Bilirubin and Indirect Bilirubin for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Change from Baseline in clinical chemistry parameters: Bilirubin, Creatinine, Direct Bilirubin and Indirect Bilirubin for participants who never received 100 mg open label Sirukumab in Part B
End point description:	
Blood samples were collected to analyze the chemistry parameters including Albumin and Protein. Change from Baseline is presented for these parameters. Baseline was defined as the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Data for participants who never received 100 mg open label Sirukumab has been presented.	
End point type	Secondary
End point timeframe:	
Baseline (Week 0) and Weeks 4,8,12,16,24 and 36	

End point values	PartBSIR 100 mg SC q2w+6 month prednisone	PartBSIR 100 mg SC q2w+3 month prednisone	PartBSIR 50 mg SC q4w+6 month prednisone	PartBPlacebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	4	3	3
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin,Week 4,n=3,3,2,1,2	0.7 (± 3.06)	1.3 (± 3.06)	-5.0 (± 1.41)	0.0 (± 99999)
Bilirubin,Week 8,n=2,1,2,0,2	3.0 (± 4.24)	2.0 (± 99999)	-4.0 (± 2.83)	99999 (± 99999)
Bilirubin,Week 12,n=1,1,1,1,1	4.0 (± 99999)	-2.0 (± 99999)	2.0 (± 99999)	4.0 (± 99999)
Bilirubin,Week 16,n=0,1,1,1,0	99999 (± 99999)	-2.0 (± 99999)	-2.0 (± 99999)	4.0 (± 99999)

Bilirubin,Week 24,n=0,1,0,0,0	99999 (± 99999)	-2.0 (± 99999)	99999 (± 99999)	99999 (± 99999)
Bilirubin,Week 36,n=0,1,0,0,0	99999 (± 99999)	-4.0 (± 99999)	99999 (± 99999)	99999 (± 99999)
Direct Bilirubin,Week 4,n=3,3,2,1,2	0.0 (± 0.00)	0.0 (± 0.00)	0.0 (± 0.00)	0.0 (± 99999)
Direct Bilirubin,Week 8,n=2,1,2,0,2	1.0 (± 1.41)	2.0 (± 99999)	0.0 (± 0.00)	99999 (± 99999)
Direct Bilirubin,Week 12,n=1,1,1,1,1	2.0 (± 99999)	2.0 (± 99999)	0.0 (± 99999)	0.0 (± 99999)
Direct Bilirubin,Week 16,n=0,1,1,1,0	99999 (± 99999)	0.0 (± 99999)	0.0 (± 99999)	0.0 (± 99999)
Direct Bilirubin,Week 24,n=0,1,0,0,0	99999 (± 99999)	0.0 (± 99999)	99999 (± 99999)	99999 (± 99999)
Direct Bilirubin,Week 36,n=0,1,0,0,0	99999 (± 99999)	0.0 (± 99999)	99999 (± 99999)	99999 (± 99999)
Indirect Bilirubin,Week 4,n=3,3,2,1,2	0.7 (± 3.06)	1.3 (± 3.06)	-5.0 (± 1.41)	0.0 (± 99999)
Indirect Bilirubin,Week 8,n=2,1,2,0,2	2.0 (± 2.83)	0.0 (± 99999)	-4.0 (± 2.83)	99999 (± 99999)
Indirect Bilirubin,Week 12,n=1,1,1,1,1	2.0 (± 99999)	-4.0 (± 99999)	2.0 (± 99999)	4.0 (± 99999)
Indirect Bilirubin,Week 16,n=0,1,1,1,0	99999 (± 99999)	-2.0 (± 99999)	-2.0 (± 99999)	4.0 (± 99999)
Indirect Bilirubin,Week 24,n=0,1,0,0,0	99999 (± 99999)	-2.0 (± 99999)	99999 (± 99999)	99999 (± 99999)
Indirect Bilirubin,Week 36,n=0,1,0,0,0	99999 (± 99999)	-4.0 (± 99999)	99999 (± 99999)	99999 (± 99999)
Creatinine,Week 4,n=3,3,2,1,2	-7.07 (± 7.887)	-0.63 (± 4.842)	-1.30 (± 9.334)	-0.90 (± 99999)
Creatinine,Week 8,n=2,1,2,0,2	-8.40 (± 0.566)	-18.60 (± 99999)	-5.25 (± 3.748)	99999 (± 99999)
Creatinine,Week 12,n=1,1,1,1,1	-6.20 (± 99999)	-27.40 (± 99999)	5.30 (± 99999)	9.70 (± 99999)
Creatinine,Week 16,n=0,1,1,1,0	99999 (± 99999)	-19.50 (± 99999)	5.30 (± 99999)	5.30 (± 99999)
Creatinine,Week 24,n=0,1,0,0,0	99999 (± 99999)	-27.40 (± 99999)	99999 (± 99999)	99999 (± 99999)
Creatinine,Week 36,n=0,1,0,0,0	99999 (± 99999)	-21.20 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartBPlacebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Bilirubin,Week 4,n=3,3,2,1,2	-8.0 (± 2.83)			
Bilirubin,Week 8,n=2,1,2,0,2	-6.0 (± 5.66)			
Bilirubin,Week 12,n=1,1,1,1,1	-8.0 (± 99999)			
Bilirubin,Week 16,n=0,1,1,1,0	99999 (± 99999)			
Bilirubin,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Bilirubin,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Direct Bilirubin,Week 4,n=3,3,2,1,2	-2.0 (± 0.00)			
Direct Bilirubin,Week 8,n=2,1,2,0,2	-2.0 (± 0.00)			

Direct Bilirubin,Week 12,n=1,1,1,1,1	-2.0 (± 99999)			
Direct Bilirubin,Week 16,n=0,1,1,1,0	99999 (± 99999)			
Direct Bilirubin,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Direct Bilirubin,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Indirect Bilirubin,Week 4,n=3,3,2,1,2	-6.0 (± 2.83)			
Indirect Bilirubin,Week 8,n=2,1,2,0,2	-4.0 (± 5.66)			
Indirect Bilirubin,Week 12,n=1,1,1,1,1	-6.0 (± 99999)			
Indirect Bilirubin,Week 16,n=0,1,1,1,0	99999 (± 99999)			
Indirect Bilirubin,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Indirect Bilirubin,Week 36,n=0,1,0,0,0	99999 (± 99999)			
Creatinine,Week 4,n=3,3,2,1,2	3.95 (± 19.445)			
Creatinine,Week 8,n=2,1,2,0,2	-5.75 (± 5.728)			
Creatinine,Week 12,n=1,1,1,1,1	-19.50 (± 99999)			
Creatinine,Week 16,n=0,1,1,1,0	99999 (± 99999)			
Creatinine,Week 24,n=0,1,0,0,0	99999 (± 99999)			
Creatinine,Week 36,n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Cumulative prednisone dose over time for participants who received at least one dose of 100 mg open-label Sirukumab in Part B

End point title	Part B: Cumulative prednisone dose over time for participants who received at least one dose of 100 mg open-label Sirukumab in Part B
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End point description:

Cumulative prednisone dose is the cumulative doses taken from start of Part B. The cumulative prednisone dose at each visit was calculated based on the number of participants who attended that visit. Data for participants who received at least one dose of 100mg open label Sirukumab was presented.

End point type	Secondary
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End point timeframe:

Weeks 2, 4, 8, 12, 14, 16, 24, 28, 32 and 38

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Milligrams				
arithmetic mean (standard deviation)				
Week 2, n=0,0,0,1,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	561.000 (± 99999)
Week 4,n=0,0,0,2,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	596.125 (± 586.7219)
Week 8,n=0,0,0,2,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	956.125 (± 851.8869)
Week 12,n=0,0,0,2,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1201.125 (± 1000.3793)
Week 14,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	843.750 (± 99999)
Week 16,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1233.750 (± 99999)
Week 24,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1853.750 (± 99999)
Week 28,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1908.500 (± 99999)
Week 32,n=0,0,0,0,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 38,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	2153.750 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Milligrams				
arithmetic mean (standard deviation)				
Week 2, n=0,0,0,1,1	550.000 (± 99999)			
Week 4,n=0,0,0,2,1	775.000 (± 99999)			
Week 8,n=0,0,0,2,0	99999 (± 99999)			
Week 12,n=0,0,0,2,1	1600.000 (± 99999)			
Week 14,n=0,0,0,1,0	99999 (± 99999)			
Week 16,n=0,0,0,1,0	99999 (± 99999)			
Week 24,n=0,0,0,1,0	99999 (± 99999)			
Week 28,n=0,0,0,1,0	99999 (± 99999)			
Week 32,n=0,0,0,0,1	1600.000 (± 99999)			
Week 38,n=0,0,0,1,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Cumulative prednisone dose over time for participants who never received 100 mg open label Sirukumab in Part B

End point title	Part B: Cumulative prednisone dose over time for participants who never received 100 mg open label Sirukumab in Part B
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End point description:

Cumulative prednisone dose is the cumulative doses taken from start of Part B. The cumulative prednisone dose at each visit was calculated based on the number of participants who attended that visit. Data for participants who never received 100 mg open label Sirukumab has been presented.

End point type	Secondary
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End point timeframe:

Weeks 2, 4, 8, 12, 14, 16, 24, 28, 32 and 38

End point values	PartBSIR 100 mg SC q2w+6 month prednisone	PartBSIR 100 mg SC q2w+3 month prednisone	PartBSIR 50 mg SC q4w+6 month prednisone	PartBPlacebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	4	3	3
Units: Milligrams				
arithmetic mean (standard deviation)				
Week 2, n=0,0,0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 4,n=0,0,0,1,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	203.750 (± 99999)
Week 8,n=0,0,0,1,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	357.500 (± 99999)
Week 12,n=0,0,0,0,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 14,n=0,0,0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 16,n=0,0,0,0,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 24,n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	397.500 (± 99999)
Week 28,n= 0,0,0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 32,n=0,0,0,0,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 38,n=0,0,0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartBPlacebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Milligrams				
arithmetic mean (standard deviation)				
Week 2, n=0,0,0,0,0	99999 (± 99999)			
Week 4,n=0,0,0,1,1	325.000 (± 99999)			
Week 8,n=0,0,0,1,1	596.250 (± 99999)			
Week 12,n=0,0,0,0,1	830.000 (± 99999)			
Week 14,n=0,0,0,0,0	99999 (± 99999)			
Week 16,n=0,0,0,0,1	1020.000 (± 99999)			
Week 24,n=0,0,0,1,0	99999 (± 99999)			
Week 28,n= 0,0,0,0,0	99999 (± 99999)			
Week 32,n=0,0,0,0,1	1211.250 (± 99999)			
Week 38,n=0,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of disease flares over time

End point title	Part B: Number of disease flares over time
End point description:	
This summarizes disease flares over time with no adjustment for exposure to study drugs, calculated by taking the last visit before a participant withdrew and then counting the number of participants with at least 1 flare up to that point and summing up the total number of flares experienced by each of these participants. Data for number of disease flares per participant over time for part B were presented.	
End point type	Secondary
End point timeframe:	
Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40	

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	5	4	5
Units: Disease flares				
Week 2, n=1,1,0,1,2				

Week 4, n=5,4,4,3,4				
Week 8, n=4,2,3,2,3				
Week 12, n=3,2,2,2,1				
Week 14, n=0,0,0,1,0				
Week 16, n=2,1,1,2,0				
Week 24, n=2,1,0,0,0				
Week 36, n=2,1,0,0,0				
Week 38, n=1,0,0,0,0				
Week 40, n=1,0,0,0,0				

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	4			
Units: Disease flares				
Week 2, n=1,1,0,1,2				
Week 4, n=5,4,4,3,4				
Week 8, n=4,2,3,2,3				
Week 12, n=3,2,2,2,1				
Week 14, n=0,0,0,1,0				
Week 16, n=2,1,1,2,0				
Week 24, n=2,1,0,0,0				
Week 36, n=2,1,0,0,0				
Week 38, n=1,0,0,0,0				
Week 40, n=1,0,0,0,0				

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of participants requiring at least one hospitalization for disease flare

End point title	Part B: Number of participants requiring at least one hospitalization for disease flare
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End point description:

Number of participants with at least one flare at a given visit was the number of participants with at least one flare between first SC IP intake and the day of the given visit. The hospitalizations for disease flare were planned to be identified through the adjudication of adverse events of special interest, and include events from the category: "Severe Flare including Hospitalizations". Data for participants requiring hospitalizations for disease flare for part B was not available due to early termination of study.

End point type	Secondary
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End point timeframe:

Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	5	4	5
Units: Participants	9999999	9999999	9999999	9999999

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	4			
Units: Participants	9999999			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of hospitalizations for disease flare over time

End point title	Part B: Number of hospitalizations for disease flare over time
End point description:	
Number of participants with at least one flare at a given visit was the number of participants with at least one flare between first SC IP intake and the day of the given visit. The hospitalizations for disease flare were planned to be identified through the adjudication of adverse events of special interest, and include events from the category: "Severe Flare including Hospitalizations". Data for participants requiring hospitalizations for disease flare for part B was not available due to early termination of study.	
End point type	Secondary
End point timeframe:	
Up to Week 104	

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	5	4	5
Units: Number of hospitalizations	9999999	9999999	9999999	9999999

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	4			

Units: Number of hospitalizations	9999999			
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Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in 36-item SF-36 v2 acute score over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in 36-item SF-36 v2 acute score over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B
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End point description:

SF-36v2 acute health survey questionnaire was developed as part of the Rand Health Insurance Experiment and consists of the following 8 multi-item scales: 1. Limitations in physical functioning due to health problems, 2. Limitations in usual role activities due to physical health problems, 3. Bodily pain, 4. General mental health (psychological distress and well-being), 5. Limitations in usual role activities due to personal or emotional problems, 6. Limitations in social functioning due to physical or mental health problems. 7. Vitality (energy and fatigue) and 8. General health perception. These 8 scales were scored from 0 to 100, 0 (worst score) to 100 (best score) where higher scores indicates better health. Data for participants (Par) who received at least one dose of 100 mg OL Sirukumab has been presented. Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Day 0), Day 85, Day 87, Day 91, Day 113, Day 162, Day 339, Day 344, Week 12 and Week 24

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Scores on scale				
number (not applicable)				
Par 1, Week 12, Physical Functioning	10	99999	99999	99999
Par 1, Week 12, Role Physical	12.5	99999	99999	99999
Par 1, Week 12, Bodily Pain	-39	99999	99999	99999
Par 1, Week 12, General Health	0	99999	99999	99999
Par 1, Week 12, Vitality	-6.25	99999	99999	99999
Par 1, Week 12, Social Functioning	0	99999	99999	99999
Par 1, Week 12, Role Emotional	-8.33	99999	99999	99999
Par 1, Week 12, Mental Health	10	99999	99999	99999
Par 1, Week 12, Physical Component Summary	-8.76	99999	99999	99999
Par 1, Week 12, Mental Component Summary	3.29	99999	99999	99999
Par 1, Week 24, Physical Functioning	-4.99	99999	99999	99999
Par 1, Week 24, Role Physical	-12.5	99999	99999	99999

Par 1, Week 24, Bodily Pain	1	99999	99999	99999
Par 1, Week 24, General Health	-5	99999	99999	99999
Par 1, Week 24, Vitality	0	99999	99999	99999
Par 1, Week 24, Social Functioning	0	99999	99999	99999
Par 1, Week 24, Role Emotional	-16.67	99999	99999	99999
Par 1, Week 24, Mental Health	5	99999	99999	99999
Par 1, Week 24, Physical Component Summary	-2.09	99999	99999	99999
Par 1, Week 24, Mental Component Summary	-0.76	99999	99999	99999
Par 1, Day 339, Physical Functioning	9.99	99999	99999	99999
Par 1, Day 339, Role Physical	37.5	99999	99999	99999
Par 1, Day 339, Bodily Pain	23	99999	99999	99999
Par 1, Day 339, General Health	5	99999	99999	99999
Par 1, Day 339, Vitality	6.25	99999	99999	99999
Par 1, Day 339, Social Functioning	0	99999	99999	99999
Par 1, Day 339, Role Emotional	0	99999	99999	99999
Par 1, Day 339, Mental Health	0	99999	99999	99999
Par 1, Day 339, Physical Component Summary	9.98	99999	99999	99999
Par 1, Day 339, Mental Component Summary	-2.78	99999	99999	99999
Par 2, Week 12, Physical Functioning	4.99	99999	99999	99999
Par 2, Week 12, Role Physical	50	99999	99999	99999
Par 2, Week 12, Bodily Pain	49	99999	99999	99999
Par 2, Week 12, General Health	10	99999	99999	99999
Par 2, Week 12, Vitality	0	99999	99999	99999
Par 2, Week 12, Social Functioning	12.5	99999	99999	99999
Par 2, Week 12, Role Emotional	99999	99999	99999	99999
Par 2, Week 12, Mental Health	-10	99999	99999	99999
Par 2, Week 12, Physical Component Summary	15.7	99999	99999	99999
Par 2, Week 12, Mental Component Summary	-5.84	99999	99999	99999
Par 2, Week 24, Physical Functioning	24.99	99999	99999	99999
Par 2, Week 24, Role Physical	50	99999	99999	99999
Par 2, Week 24, Bodily Pain	33	99999	99999	99999
Par 2, Week 24, General Health	5	99999	99999	99999
Par 2, Week 24, Vitality	-6.25	99999	99999	99999
Par 2, Week 24, Social Functioning	12.5	99999	99999	99999
Par 2, Week 24, Role Emotional	0	99999	99999	99999
Par 2, Week 24, Mental Health	-20	99999	99999	99999
Par 2, Week 24, Physical Component Summary	17.37	99999	99999	99999
Par 2, Week 24, Mental Component Summary	-10.18	99999	99999	99999
Par 2, Day 344, Physical Functioning	-5.01	99999	99999	99999
Par 2, Day 344, Role Physical	37.5	99999	99999	99999
Par 2, Day 344, Bodily Pain	11	99999	99999	99999
Par 2, Day 344, General Health	10	99999	99999	99999
Par 2, Day 344, Vitality	-6.25	99999	99999	99999
Par 2, Day 344, Social Functioning	12.5	99999	99999	99999
Par 2, Day 344, Role Emotional	0	99999	99999	99999
Par 2, Day 344, Mental Health	-15	99999	99999	99999

Par 2, Day 344, Physical Component Summary	8.12	99999	99999	99999
Par 2, Day 344, Mental Component Summary	-4.89	99999	99999	99999
Par 3, Day 113, Physical Functioning	99999	99999	-10	99999
Par 3, Day 113, Role Physical	99999	99999	0	99999
Par 3, Day 113, Bodily Pain	99999	99999	0	99999
Par 3, Day 113, General Health	99999	99999	-5	99999
Par 3, Day 113, Vitality	99999	99999	-6.25	99999
Par 3, Day 113, Social Functioning	99999	99999	99999	99999
Par 3, Day 113, Role Emotional	99999	99999	0	99999
Par 3, Day 113, Mental Health	99999	99999	-5	99999
Par 3, Day 113, Physical Component Summary	99999	99999	-1.72	99999
Par 3, Day 113, Mental Component Summary	99999	99999	-1.05	99999
Par 4, Week 12, Physical Functioning	99999	15	99999	99999
Par 4, Week 12, Role Physical	99999	6.25	99999	99999
Par 4, Week 12, Bodily Pain	99999	33	99999	99999
Par 4, Week 12, General Health	99999	-5	99999	99999
Par 4, Week 12, Vitality	99999	0	99999	99999
Par 4, Week 12, Social Functioning	99999	0	99999	99999
Par 4, Week 12, Role Emotional	99999	0	99999	99999
Par 4, Week 12, Mental Health	99999	5	99999	99999
Par 4, Week 12, Physical Component Summary	99999	6.28	99999	99999
Par 4, Week 12, Mental Component Summary	99999	-1.59	99999	99999
Par 5, Week 12, Physical Functioning	99999	99999	99999	5
Par 5, Week 12, Role Physical	99999	99999	99999	-18.75
Par 5, Week 12, Bodily Pain	99999	99999	99999	-16
Par 5, Week 12, General Health	99999	99999	99999	10
Par 5, Week 12, Vitality	99999	99999	99999	6.25
Par 5, Week 12, Social Functioning	99999	99999	99999	-25
Par 5, Week 12, Role Emotional	99999	99999	99999	-16.66
Par 5, Week 12, Mental Health	99999	99999	99999	-5
Par 5, Week 12, Physical Component Summary	99999	99999	99999	-0.34
Par 5, Week 12, Mental Component Summary	99999	99999	99999	-5.35
Par 5, Day 162, Physical Functioning	99999	99999	99999	10.01
Par 5, Day 162, Role Physical	99999	99999	99999	-18.75
Par 5, Day 162, Bodily Pain	99999	99999	99999	-16
Par 5, Day 162, General Health	99999	99999	99999	-7
Par 5, Day 162, Vitality	99999	99999	99999	-12.5
Par 5, Day 162, Social Functioning	99999	99999	99999	-25
Par 5, Day 162, Role Emotional	99999	99999	99999	-33.33
Par 5, Day 162, Mental Health	99999	99999	99999	5
Par 5, Day 162, Physical Component Summary	168	99999	99999	-1.62
Par 5, Day 162, Mental Component Summary	99999	99999	99999	-8.24
Par 6, Day 91, Physical Functioning	99999	99999	99999	-15
Par 6, Day 91, Role Physical	99999	99999	99999	-25
Par 6, Day 91, Bodily Pain	99999	99999	99999	22

Par 6, Day 91, General Health	99999	99999	99999	0
Par 6, Day 91, Vitality	99999	99999	99999	-6.25
Par 6, Day 91, Social Functioning	99999	99999	99999	0
Par 6, Day 91, Role Emotional	99999	99999	99999	0
Par 6, Day 91, Mental Health	99999	99999	99999	20
Par 6, Day 91, Physical Component Summary	99999	99999	99999	-5.17
Par 6, Day 91, Mental Component Summary	99999	99999	99999	5.95
Par 7, Day 85, Physical Functioning	99999	99999	99999	99999
Par 7, Day 85, Role Physical	99999	99999	99999	99999
Par 7, Day 85, Bodily Pain	99999	99999	99999	99999
Par 7, Day 85, General Health	99999	99999	99999	99999
Par 7, Day 85, Vitality	99999	99999	99999	99999
Par 7, Day 85, Social Functioning	99999	99999	99999	99999
Par 7, Day 85, Role Emotional	99999	99999	99999	99999
Par 7, Day 85, Mental Health	99999	99999	99999	99999
Par 7, Day 85, Physical Component Summary	99999	99999	99999	99999
Par 7, Day 85, Mental Component Summary	99999	99999	99999	99999
Par 8, Day 87, Physical Functioning	99999	99999	99999	99999
Par 8, Day 87, Role Physical	99999	99999	99999	99999
Par 8, Day 87, Bodily Pain	99999	99999	99999	99999
Par 8, Day 87, General Health	99999	99999	99999	99999
Par 8, Day 87, Vitality	99999	99999	99999	99999
Par 8, Day 87, Social Functioning	99999	99999	99999	99999
Par 8, Day 87, Role Emotional	99999	99999	99999	99999
Par 8, Day 87, Mental Health	99999	99999	99999	99999
Par 8, Day 87, Physical Component Summary	99999	99999	99999	99999
Par 8, Day 87, Mental Component Summary	99999	99999	99999	99999

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Scores on scale				
number (not applicable)				
Par 1, Week 12, Physical Functioning	99999			
Par 1, Week 12, Role Physical	99999			
Par 1, Week 12, Bodily Pain	99999			
Par 1, Week 12, General Health	99999			
Par 1, Week 12, Vitality	99999			
Par 1, Week 12, Social Functioning	99999			
Par 1, Week 12, Role Emotional	99999			
Par 1, Week 12, Mental Health	99999			
Par 1, Week 12, Physical Component Summary	99999			

Par 1, Week 12, Mental Component Summary	99999			
Par 1, Week 24, Physical Functioning	99999			
Par 1, Week 24, Role Physical	99999			
Par 1, Week 24, Bodily Pain	99999			
Par 1, Week 24, General Health	99999			
Par 1, Week 24, Vitality	99999			
Par 1, Week 24, Social Functioning	99999			
Par 1, Week 24, Role Emotional	99999			
Par 1, Week 24, Mental Health	99999			
Par 1, Week 24, Physical Component Summary	99999			
Par 1, Week 24, Mental Component Summary	99999			
Par 1, Day 339, Physical Functioning	99999			
Par 1, Day 339, Role Physical	99999			
Par 1, Day 339, Bodily Pain	99999			
Par 1, Day 339, General Health	99999			
Par 1, Day 339, Vitality	99999			
Par 1, Day 339, Social Functioning	99999			
Par 1, Day 339, Role Emotional	99999			
Par 1, Day 339, Mental Health	99999			
Par 1, Day 339, Physical Component Summary	99999			
Par 1, Day 339, Mental Component Summary	99999			
Par 2, Week 12, Physical Functioning	99999			
Par 2, Week 12, Role Physical	99999			
Par 2, Week 12, Bodily Pain	99999			
Par 2, Week 12, General Health	99999			
Par 2, Week 12, Vitality	99999			
Par 2, Week 12, Social Functioning	99999			
Par 2, Week 12, Role Emotional	99999			
Par 2, Week 12, Mental Health	99999			
Par 2, Week 12, Physical Component Summary	99999			
Par 2, Week 12, Mental Component Summary	99999			
Par 2, Week 24, Physical Functioning	99999			
Par 2, Week 24, Role Physical	99999			
Par 2, Week 24, Bodily Pain	99999			
Par 2, Week 24, General Health	99999			
Par 2, Week 24, Vitality	99999			
Par 2, Week 24, Social Functioning	99999			
Par 2, Week 24, Role Emotional	99999			
Par 2, Week 24, Mental Health	99999			
Par 2, Week 24, Physical Component Summary	99999			
Par 2, Week 24, Mental Component Summary	99999			
Par 2, Day 344, Physical Functioning	99999			
Par 2, Day 344, Role Physical	99999			
Par 2, Day 344, Bodily Pain	99999			
Par 2, Day 344, General Health	99999			
Par 2, Day 344, Vitality	99999			

Par 2, Day 344, Social Functioning	99999			
Par 2, Day 344, Role Emotional	99999			
Par 2, Day 344, Mental Health	99999			
Par 2, Day 344, Physical Component Summary	99999			
Par 2, Day 344, Mental Component Summary	99999			
Par 3, Day 113, Physical Functioning	99999			
Par 3, Day 113, Role Physical	99999			
Par 3, Day 113, Bodily Pain	99999			
Par 3, Day 113, General Health	99999			
Par 3, Day 113, Vitality	99999			
Par 3, Day 113, Social Functioning	99999			
Par 3, Day 113, Role Emotional	99999			
Par 3, Day 113, Mental Health	99999			
Par 3, Day 113, Physical Component Summary	99999			
Par 3, Day 113, Mental Component Summary	99999			
Par 4, Week 12, Physical Functioning	99999			
Par 4, Week 12, Role Physical	99999			
Par 4, Week 12, Bodily Pain	99999			
Par 4, Week 12, General Health	99999			
Par 4, Week 12, Vitality	99999			
Par 4, Week 12, Social Functioning	99999			
Par 4, Week 12, Role Emotional	99999			
Par 4, Week 12, Mental Health	99999			
Par 4, Week 12, Physical Component Summary	99999			
Par 4, Week 12, Mental Component Summary	99999			
Par 5, Week 12, Physical Functioning	99999			
Par 5, Week 12, Role Physical	99999			
Par 5, Week 12, Bodily Pain	99999			
Par 5, Week 12, General Health	10			
Par 5, Week 12, Vitality	99999			
Par 5, Week 12, Social Functioning	99999			
Par 5, Week 12, Role Emotional	99999			
Par 5, Week 12, Mental Health	99999			
Par 5, Week 12, Physical Component Summary	99999			
Par 5, Week 12, Mental Component Summary	99999			
Par 5, Day 162, Physical Functioning	99999			
Par 5, Day 162, Role Physical	99999			
Par 5, Day 162, Bodily Pain	99999			
Par 5, Day 162, General Health	99999			
Par 5, Day 162, Vitality	99999			
Par 5, Day 162, Social Functioning	99999			
Par 5, Day 162, Role Emotional	99999			
Par 5, Day 162, Mental Health	99999			
Par 5, Day 162, Physical Component Summary	99999			
Par 5, Day 162, Mental Component Summary	99999			

Par 6, Day 91, Physical Functioning	99999			
Par 6, Day 91, Role Physical	99999			
Par 6, Day 91, Bodily Pain	99999			
Par 6, Day 91, General Health	99999			
Par 6, Day 91, Vitality	99999			
Par 6, Day 91, Social Functioning	99999			
Par 6, Day 91, Role Emotional	99999			
Par 6, Day 91, Mental Health	99999			
Par 6, Day 91, Physical Component Summary	99999			
Par 6, Day 91, Mental Component Summary	99999			
Par 7, Day 85, Physical Functioning	-10.01			
Par 7, Day 85, Role Physical	-6.25			
Par 7, Day 85, Bodily Pain	-22			
Par 7, Day 85, General Health	10			
Par 7, Day 85, Vitality	-12.5			
Par 7, Day 85, Social Functioning	99999			
Par 7, Day 85, Role Emotional	99999			
Par 7, Day 85, Mental Health	5			
Par 7, Day 85, Physical Component Summary	-4.79			
Par 7, Day 85, Mental Component Summary	1.82			
Par 8, Day 87, Physical Functioning	0			
Par 8, Day 87, Role Physical	6.25			
Par 8, Day 87, Bodily Pain	21			
Par 8, Day 87, General Health	0			
Par 8, Day 87, Vitality	0			
Par 8, Day 87, Social Functioning	12.5			
Par 8, Day 87, Role Emotional	16.66			
Par 8, Day 87, Mental Health	5			
Par 8, Day 87, Physical Component Summary	1.52			
Par 8, Day 87, Mental Component Summary	4.54			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in 36-item SF-36 v2 acute score over time for participants who never received 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in 36-item SF-36 v2 acute score over time for participants who never received 100 mg OL Sirukumab in Part B
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End point description:

SF-36v2 acute health survey questionnaire was developed as part of the Rand Health Insurance Experiment and consists of the following 8 multi-item scales: 1. Limitations in physical functioning due to health problems, 2. Limitations in usual role activities due to physical health problems, 3. Bodily pain, 4. General mental health (psychological distress and well-being), 5. Limitations in usual role activities due to personal or emotional problems, 6. Limitations in social functioning due to physical or mental health problems. 7. Vitality (energy and fatigue) and 8. General health perception. These 8 scales were scored from 0 to 100, 0 (worst score) to 100 (best score) where higher scores indicates better health.

Data for participants (Par) who never received 100 mg OL Sirukumab has been presented. Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
End point timeframe:	
Baseline (Day 0) and Day 23, Day 29, Day 30, Day 57, Day 59, Day 64, Day 65 , Day 85, Day 112, Day 113, Day 163, Day 169, Day 373, Week 8 and Week 12	

End point values	PartB:Placebo SC q2w + 6 month prednisone	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	2	6	4
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30, Physical Functioning	99999	99999	-5	99999
Par 1, Day 30, Role Physical	99999	99999	0	99999
Par 1, Day 30, Bodily Pain	99999	99999	-16	99999
Par 1, Day 30, General health	99999	99999	10	99999
Par 1, Day 30, Vitality	99999	99999	0	99999
Par 1, Day 30, Social Functioning	99999	99999	0	99999
Par 1, Day 30, Role emotional	99999	99999	0	99999
Par 1, Day 30, Mental health	99999	99999	5	99999
Par 1, Day 30, Physical Component Summary	99999	99999	-2.26	99999
Par 1, Day 30, Mental Component Summary	99999	99999	2.26	99999
Par 2, Day 29, Physical Functioning	99999	99999	0	99999
Par 2, Day 29, Role Physical	99999	99999	0	99999
Par 2, Day 29, Bodily Pain	99999	99999	0	99999
Par 2, Day 29, General health	99999	99999	8	99999
Par 2, Day 29, Vitality	99999	99999	6.25	99999
Par 2, Day 29, Social Functioning	99999	99999	0	99999
Par 2, Day 29, Role emotional	99999	99999	0	99999
Par 2, Day 29, Mental health	99999	99999	10	99999
Par 2, Day 29, Physical Component Summary	99999	99999	-0.12	99999
Par 2, Day 29, Mental Component Summary	99999	99999	3.18	99999
Par 3, Day 23, Physical Functioning	99999	99999	25	99999
Par 3, Day 23, Role Physical	99999	99999	6.25	99999
Par 3, Day 23, Bodily Pain	99999	99999	49	99999
Par 3, Day 23, General health	99999	99999	10	99999
Par 3, Day 23, Vitality	99999	99999	0	99999
Par 3, Day 23, Social Functioning	99999	99999	0	99999
Par 3, Day 23, Role emotional	99999	99999	0	99999
Par 3, Day 23, Mental health	99999	99999	-5	99999
Par 3, Day 23, Physical Component Summary	99999	99999	12.88	99999
Par 3, Day 23, Mental Component Summary	99999	99999	-5.75	99999
Par 4, Week 12, Physical Functioning	99999	99999	15	99999

Par 4, Week 12, Role Physical	99999	99999	18.75	99999
Par 4, Week 12, Bodily Pain	99999	99999	0	99999
Par 4, Week 12, General health	99999	99999	0	99999
Par 4, Week 12, Vitality	99999	99999	6.25	99999
Par 4, Week 12, Social Functioning	99999	99999	0	99999
Par 4, Week 12, Role emotional	99999	99999	0	99999
Par 4, Week 12, Mental health	99999	99999	0	99999
Par 4, Week 12, Physical Component Summary	99999	99999	4.88	99999
Par 4, Week 12, Mental Component Summary	99999	99999	-1.45	99999
Par 4, Day 113, Physical Functioning	99999	99999	15	99999
Par 4, Day 113, Role Physical	99999	99999	0	99999
Par 4, Day 113, Bodily Pain	99999	99999	0	99999
Par 4, Day 113, General health	99999	99999	10	99999
Par 4, Day 113, Vitality	99999	99999	0	99999
Par 4, Day 113, Social Functioning	99999	99999	-12.5	99999
Par 4, Day 113, Role emotional	99999	99999	0	99999
Par 4, Day 113, Mental health	99999	99999	25	99999
Par 4, Day 113, Physical Component Summary	99999	99999	0.77	99999
Par 4, Day 113, Mental Component Summary	99999	99999	3.61	99999
Par 5, Week 8, Physical Functioning	99999	99999	-5	99999
Par 5, Week 8, Role Physical	99999	99999	0	99999
Par 5, Week 8, Bodily Pain	99999	99999	10	99999
Par 5, Week 8, General health	99999	99999	-10	99999
Par 5, Week 8, Vitality	99999	99999	-6.25	99999
Par 5, Week 8, Social Functioning	99999	99999	-12.5	99999
Par 5, Week 8, Role emotional	99999	99999	16.67	99999
Par 5, Week 8, Mental health	99999	99999	0	99999
Par 5, Week 8, Physical Component Summary	99999	99999	-2.1	99999
Par 5, Week 8, Mental Component Summary	99999	99999	1.1	99999
Par 5, Day 85, Physical Functioning	99999	99999	5	99999
Par 5, Day 85, Role Physical	99999	99999	-6.25	99999
Par 5, Day 85, Bodily Pain	99999	99999	10	99999
Par 5, Day 85, General health	99999	99999	-22	99999
Par 5, Day 85, Vitality	99999	99999	-6.25	99999
Par 5, Day 85, Social Functioning	99999	99999	-12.5	99999
Par 5, Day 85, Role emotional	99999	99999	8.33	99999
Par 5, Day 85, Mental health	99999	99999	10	99999
Par 5, Day 85, Physical Component Summary	99999	99999	-3.17	99999
Par 5, Day 85, Mental Component Summary	99999	99999	1.62	99999
Par 6, Day 65, Physical Functioning	99999	99999	0	99999
Par 6, Day 65, Role Physical	99999	99999	6.25	99999
Par 6, Day 65, Bodily Pain	99999	99999	0	99999
Par 6, Day 65, General health	99999	99999	0	99999
Par 6, Day 65, Vitality	99999	99999	-6.25	99999
Par 6, Day 65, Social Functioning	99999	99999	12.5	99999
Par 6, Day 65, Role emotional	99999	99999	8.33	99999

Par 6, Day 65, Mental health	99999	99999	0	99999
Par 6, Day 65, Physical Component Summary	99999	99999	-0.01	99999
Par 6, Day 65, Mental Component Summary	99999	99999	1.88	99999
Par 7, Week 12, Physical Functioning	99999	99999	99999	0
Par 7, Week 12, Role Physical	99999	99999	99999	6.25
Par 7, Week 12, Bodily Pain	99999	99999	99999	16
Par 7, Week 12, General health	99999	99999	99999	0
Par 7, Week 12, Vitality	99999	99999	99999	-6.25
Par 7, Week 12, Social Functioning	99999	99999	99999	0
Par 7, Week 12, Role emotional	99999	99999	99999	0
Par 7, Week 12, Mental health	99999	99999	99999	-5
Par 7, Week 12, Physical Component Summary	99999	99999	99999	-3.33
Par 7, Week 12, Mental Component Summary	99999	99999	99999	-2.88
Par 7, Day 373, Physical Functioning	99999	99999	99999	15
Par 7, Day 373, Role Physical	99999	99999	99999	6.25
Par 7, Day 373, Bodily Pain	99999	99999	99999	16
Par 7, Day 373, General health	99999	99999	99999	8
Par 7, Day 373, Vitality	99999	99999	99999	0
Par 7, Day 373, Social Functioning	99999	99999	99999	0
Par 7, Day 373, Role emotional	99999	99999	99999	0
Par 7, Day 373, Mental health	99999	99999	99999	-15
Par 7, Day 373, Physical Component Summary	99999	99999	99999	7.95
Par 7, Day 373, Mental Component Summary	99999	99999	99999	-6.1
Par 8, Day 64, Physical Functioning	99999	99999	99999	5
Par 8, Day 64, Role Physical	99999	99999	99999	-6.25
Par 8, Day 64, Bodily Pain	99999	99999	99999	-22
Par 8, Day 64, General health	99999	99999	99999	0
Par 8, Day 64, Vitality	99999	99999	99999	-12.5
Par 8, Day 64, Social Functioning	99999	99999	99999	0
Par 8, Day 64, Role emotional	99999	99999	99999	25
Par 8, Day 64, Mental health	99999	99999	99999	-15
Par 8, Day 64, Physical Component Summary	99999	99999	99999	-3.24
Par 8, Day 64, Mental Component Summary	99999	99999	99999	0.02
Par 9, Day 29, Physical Functioning	99999	99999	99999	10
Par 9, Day 29, Role Physical	99999	99999	99999	6.25
Par 9, Day 29, Bodily Pain	99999	99999	99999	0
Par 9, Day 29, General health	99999	99999	99999	-3
Par 9, Day 29, Vitality	99999	99999	99999	0
Par 9, Day 29, Social Functioning	99999	99999	99999	0
Par 9, Day 29, Role emotional	99999	99999	99999	0
Par 9, Day 29, Mental health	99999	99999	99999	-10
Par 9, Day 29, Physical Component Summary	99999	99999	99999	3.22
Par 9, Day 29, Mental Component Summary	99999	99999	99999	-3.68
Par 10, Day 57, Physical Functioning	99999	99999	99999	0
Par 10, Day 57, Role Physical	99999	99999	99999	12.5

Par 10, Day 57, Bodily Pain	99999	99999	99999	0
Par 10, Day 57, General health	99999	99999	99999	-5
Par 10, Day 57, Vitality	99999	99999	99999	0
Par 10, Day 57, Social Functioning	99999	99999	99999	12.5
Par 10, Day 57, Role emotional	99999	99999	99999	0
Par 10, Day 57, Mental health	99999	99999	99999	0
Par 10, Day 57, Physical Component Summary	99999	99999	99999	0.95
Par 10, Day 57, Mental Component Summary	99999	99999	99999	0.83
Par 11, Week 12, Physical Functioning	99999	99999	99999	99999
Par 11, Week 12, Role Physical	99999	99999	99999	99999
Par 11, Week 12, Bodily Pain	99999	99999	99999	99999
Par 11, Week 12, General health	99999	99999	99999	99999
Par 11, Week 12, Vitality	99999	99999	99999	99999
Par 11, Week 12, Social Functioning	99999	99999	99999	99999
Par 11, Week 12, Role emotional	99999	99999	99999	99999
Par 11, Week 12, Mental health	99999	99999	99999	99999
Par 11, Week 12, Physical Component Summary	99999	99999	99999	99999
Par 11, Week 12, Mental Component Summary	99999	99999	99999	99999
Par 11, Day 163, Physical Functioning	99999	99999	99999	99999
Par 11, Day 163, Role Physical	99999	99999	99999	99999
Par 11, Day 163, Bodily Pain	99999	99999	99999	99999
Par 11, Day 163, General health	99999	99999	99999	99999
Par 11, Day 163, Vitality	99999	99999	99999	99999
Par 11, Day 163, Social Functioning	99999	99999	99999	99999
Par 11, Day 163, Role emotional	99999	99999	99999	99999
Par 11, Day 163, Mental health	99999	99999	99999	99999
Par 11, Day 163, Physical Component Summary	99999	99999	99999	99999
Par 11, Day 163, Mental Component Summary	99999	99999	99999	99999
Par 12, Day 85, Physical Functioning	99999	99999	99999	99999
Par 12, Day 85, Role Physical	99999	99999	99999	99999
Par 12, Day 85, Bodily Pain	99999	99999	99999	99999
Par 12, Day 85, General health	99999	99999	99999	99999
Par 12, Day 85, Vitality	99999	99999	99999	99999
Par 12, Day 85, Social Functioning	99999	99999	99999	99999
Par 12, Day 85, Role emotional	99999	99999	99999	99999
Par 12, Day 85, Mental health	99999	99999	99999	99999
Par 12, Day 85, Physical Component Summary	99999	99999	99999	99999
Par 12, Day 85, Mental Component Summary	99999	99999	99999	99999
Par 13, Day 59, Physical Functioning	99999	99999	99999	99999
Par 13, Day 59, Role Physical	99999	99999	99999	99999
Par 13, Day 59, Bodily Pain	99999	99999	99999	99999
Par 13, Day 59, General health	99999	99999	99999	99999
Par 13, Day 59, Vitality	99999	99999	99999	99999
Par 13, Day 59, Social Functioning	99999	99999	99999	99999
Par 13, Day 59, Role emotional	99999	99999	99999	99999
Par 13, Day 59, Mental health	99999	99999	99999	99999

Par 13, Day 59, Physical Component Summary	99999	99999	99999	99999
Par 13, Day 59, Mental Component Summary	99999	99999	99999	99999
Par 14, Day 57, Physical Functioning	-5.01	99999	99999	99999
Par 14, Day 57, Role Physical	-18.75	99999	99999	99999
Par 14, Day 57, Bodily Pain	-32	99999	99999	99999
Par 14, Day 57, General health	10	99999	99999	99999
Par 14, Day 57, Vitality	12.5	99999	99999	99999
Par 14, Day 57, Social Functioning	-37.5	99999	99999	99999
Par 14, Day 57, Role emotional	0	99999	99999	99999
Par 14, Day 57, Mental health	15	99999	99999	99999
Par 14, Day 57, Physical Component Summary	-7.54	99999	99999	99999
Par 14, Day 57, Mental Component Summary	3.62	99999	99999	99999
Par 15, Day 169, Physical Functioning	4.99	99999	99999	99999
Par 15, Day 169, Role Physical	50	99999	99999	99999
Par 15, Day 169, Bodily Pain	33	99999	99999	99999
Par 15, Day 169, General health	5	99999	99999	99999
Par 15, Day 169, Vitality	6.25	99999	99999	99999
Par 15, Day 169, Social Functioning	25	99999	99999	99999
Par 15, Day 169, Role emotional	50	99999	99999	99999
Par 15, Day 169, Mental health	0	99999	99999	99999
Par 15, Day 169, Physical Component Summary	7.93	99999	99999	99999
Par 15, Day 169, Mental Component Summary	8.48	99999	99999	99999
Par 16, Week 12, Physical Functioning	99999	5	99999	99999
Par 16, Week 12, Role Physical	99999	6.25	99999	99999
Par 16, Week 12, Bodily Pain	99999	28	99999	99999
Par 16, Week 12, General health	99999	0	99999	99999
Par 16, Week 12, Vitality	99999	-6.25	99999	99999
Par 16, Week 12, Social Functioning	99999	0	99999	99999
Par 16, Week 12, Role emotional	99999	0	99999	99999
Par 16, Week 12, Mental health	99999	0	99999	99999
Par 16, Week 12, Physical Component Summary	99999	5.1	99999	99999
Par 16, Week 12, Mental Component Summary	99999	-2.52	99999	99999
Par 16, Day 112, Physical Functioning	99999	0	99999	99999
Par 16, Day 112, Role Physical	99999	12.5	99999	99999
Par 16, Day 112, Bodily Pain	99999	28	99999	99999
Par 16, Day 112, General health	99999	-20	99999	99999
Par 16, Day 112, Vitality	99999	-6.25	99999	99999
Par 16, Day 112, Social Functioning	99999	0	99999	99999
Par 16, Day 112, Role emotional	99999	0	99999	99999
Par 16, Day 112, Mental health	99999	0	99999	99999
Par 16, Day 112, Physical Component Summary	99999	2.71	99999	99999
Par 16, Day 112, Mental Component Summary	99999	-2.21	99999	99999
Par 17, Day 85, Physical Functioning	99999	-10	99999	99999
Par 17, Day 85, Role Physical	99999	-25	99999	99999
Par 17, Day 85, Bodily Pain	99999	-10	99999	99999

Par 17, Day 85, General health	99999	0	99999	99999
Par 17, Day 85, Vitality	99999	6.25	99999	99999
Par 17, Day 85, Social Functioning	99999	-12.5	99999	99999
Par 17, Day 85, Role emotional	99999	0	99999	99999
Par 17, Day 85, Mental health	99999	5	99999	99999
Par 17, Day 85, Physical Component Summary	99999	-6.51	99999	99999
Par 17, Day 85, Mental Component Summary	99999	3.01	99999	99999

End point values	PartB:SIR 50 mg SC q4w+6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30, Physical Functioning	99999			
Par 1, Day 30, Role Physical	99999			
Par 1, Day 30, Bodily Pain	99999			
Par 1, Day 30, General health	99999			
Par 1, Day 30, Vitality	99999			
Par 1, Day 30, Social Functioning	99999			
Par 1, Day 30, Role emotional	99999			
Par 1, Day 30, Mental health	99999			
Par 1, Day 30, Physical Component Summary	99999			
Par 1, Day 30, Mental Component Summary	99999			
Par 2, Day 29, Physical Functioning	99999			
Par 2, Day 29, Role Physical	99999			
Par 2, Day 29, Bodily Pain	99999			
Par 2, Day 29, General health	99999			
Par 2, Day 29, Vitality	99999			
Par 2, Day 29, Social Functioning	99999			
Par 2, Day 29, Role emotional	99999			
Par 2, Day 29, Mental health	99999			
Par 2, Day 29, Physical Component Summary	99999			
Par 2, Day 29, Mental Component Summary	99999			
Par 3, Day 23, Physical Functioning	99999			
Par 3, Day 23, Role Physical	99999			
Par 3, Day 23, Bodily Pain	99999			
Par 3, Day 23, General health	99999			
Par 3, Day 23, Vitality	99999			
Par 3, Day 23, Social Functioning	99999			
Par 3, Day 23, Role emotional	99999			
Par 3, Day 23, Mental health	99999			
Par 3, Day 23, Physical Component Summary	99999			

Par 3, Day 23, Mental Component Summary	99999			
Par 4, Week 12, Physical Functioning	99999			
Par 4, Week 12, Role Physical	99999			
Par 4, Week 12, Bodily Pain	99999			
Par 4, Week 12, General health	99999			
Par 4, Week 12, Vitality	99999			
Par 4, Week 12, Social Functioning	99999			
Par 4, Week 12, Role emotional	99999			
Par 4, Week 12, Mental health	99999			
Par 4, Week 12, Physical Component Summary	99999			
Par 4, Week 12, Mental Component Summary	99999			
Par 4, Day 113, Physical Functioning	99999			
Par 4, Day 113, Role Physical	99999			
Par 4, Day 113, Bodily Pain	99999			
Par 4, Day 113, General health	99999			
Par 4, Day 113, Vitality	99999			
Par 4, Day 113, Social Functioning	99999			
Par 4, Day 113, Role emotional	99999			
Par 4, Day 113, Mental health	99999			
Par 4, Day 113, Physical Component Summary	99999			
Par 4, Day 113, Mental Component Summary	99999			
Par 5, Week 8, Physical Functioning	99999			
Par 5, Week 8, Role Physical	99999			
Par 5, Week 8, Bodily Pain	99999			
Par 5, Week 8, General health	99999			
Par 5, Week 8, Vitality	99999			
Par 5, Week 8, Social Functioning	99999			
Par 5, Week 8, Role emotional	99999			
Par 5, Week 8, Mental health	99999			
Par 5, Week 8, Physical Component Summary	99999			
Par 5, Week 8, Mental Component Summary	99999			
Par 5, Day 85, Physical Functioning	99999			
Par 5, Day 85, Role Physical	99999			
Par 5, Day 85, Bodily Pain	99999			
Par 5, Day 85, General health	99999			
Par 5, Day 85, Vitality	99999			
Par 5, Day 85, Social Functioning	99999			
Par 5, Day 85, Role emotional	99999			
Par 5, Day 85, Mental health	99999			
Par 5, Day 85, Physical Component Summary	99999			
Par 5, Day 85, Mental Component Summary	99999			
Par 6, Day 65, Physical Functioning	99999			
Par 6, Day 65, Role Physical	99999			
Par 6, Day 65, Bodily Pain	99999			
Par 6, Day 65, General health	99999			
Par 6, Day 65, Vitality	99999			

Par 6, Day 65, Social Functioning	99999			
Par 6, Day 65, Role emotional	99999			
Par 6, Day 65, Mental health	99999			
Par 6, Day 65, Physical Component Summary	99999			
Par 6, Day 65, Mental Component Summary	99999			
Par 7, Week 12, Physical Functioning	99999			
Par 7, Week 12, Role Physical	99999			
Par 7, Week 12, Bodily Pain	99999			
Par 7, Week 12, General health	99999			
Par 7, Week 12, Vitality	99999			
Par 7, Week 12, Social Functioning	99999			
Par 7, Week 12, Role emotional	99999			
Par 7, Week 12, Mental health	99999			
Par 7, Week 12, Physical Component Summary	99999			
Par 7, Week 12, Mental Component Summary	99999			
Par 7, Day 373, Physical Functioning	99999			
Par 7, Day 373, Role Physical	99999			
Par 7, Day 373, Bodily Pain	99999			
Par 7, Day 373, General health	99999			
Par 7, Day 373, Vitality	99999			
Par 7, Day 373, Social Functioning	99999			
Par 7, Day 373, Role emotional	99999			
Par 7, Day 373, Mental health	99999			
Par 7, Day 373, Physical Component Summary	99999			
Par 7, Day 373, Mental Component Summary	99999			
Par 8, Day 64, Physical Functioning	99999			
Par 8, Day 64, Role Physical	99999			
Par 8, Day 64, Bodily Pain	99999			
Par 8, Day 64, General health	99999			
Par 8, Day 64, Vitality	99999			
Par 8, Day 64, Social Functioning	99999			
Par 8, Day 64, Role emotional	99999			
Par 8, Day 64, Mental health	99999			
Par 8, Day 64, Physical Component Summary	99999			
Par 8, Day 64, Mental Component Summary	99999			
Par 9, Day 29, Physical Functioning	99999			
Par 9, Day 29, Role Physical	99999			
Par 9, Day 29, Bodily Pain	99999			
Par 9, Day 29, General health	99999			
Par 9, Day 29, Vitality	99999			
Par 9, Day 29, Social Functioning	99999			
Par 9, Day 29, Role emotional	99999			
Par 9, Day 29, Mental health	99999			
Par 9, Day 29, Physical Component Summary	99999			
Par 9, Day 29, Mental Component Summary	99999			

Par 10, Day 57, Physical Functioning	99999			
Par 10, Day 57, Role Physical	99999			
Par 10, Day 57, Bodily Pain	99999			
Par 10, Day 57, General health	99999			
Par 10, Day 57, Vitality	99999			
Par 10, Day 57, Social Functioning	99999			
Par 10, Day 57, Role emotional	99999			
Par 10, Day 57, Mental health	99999			
Par 10, Day 57, Physical Component Summary	99999			
Par 10, Day 57, Mental Component Summary	99999			
Par 11, Week 12, Physical Functioning	-29.99			
Par 11, Week 12, Role Physical	-18.75			
Par 11, Week 12, Bodily Pain	0			
Par 11, Week 12, General health	-13			
Par 11, Week 12, Vitality	-6.25			
Par 11, Week 12, Social Functioning	-25			
Par 11, Week 12, Role emotional	0			
Par 11, Week 12, Mental health	5			
Par 11, Week 12, Physical Component Summary	-9.37			
Par 11, Week 12, Mental Component Summary	1.44			
Par 11, Day 163, Physical Functioning	-15.01			
Par 11, Day 163, Role Physical	6.25			
Par 11, Day 163, Bodily Pain	0			
Par 11, Day 163, General health	-8			
Par 11, Day 163, Vitality	0			
Par 11, Day 163, Social Functioning	-37.5			
Par 11, Day 163, Role emotional	9			
Par 11, Day 163, Mental health	10			
Par 11, Day 163, Physical Component Summary	-3.64			
Par 11, Day 163, Mental Component Summary	-0.4			
Par 12, Day 85, Physical Functioning	-5			
Par 12, Day 85, Role Physical	-6.25			
Par 12, Day 85, Bodily Pain	-11			
Par 12, Day 85, General health	-5			
Par 12, Day 85, Vitality	6.25			
Par 12, Day 85, Social Functioning	0			
Par 12, Day 85, Role emotional	-16.67			
Par 12, Day 85, Mental health	5			
Par 12, Day 85, Physical Component Summary	-2.76			
Par 12, Day 85, Mental Component Summary	0.13			
Par 13, Day 59, Physical Functioning	5			
Par 13, Day 59, Role Physical	-12.5			
Par 13, Day 59, Bodily Pain	0			
Par 13, Day 59, General health	0			
Par 13, Day 59, Vitality	0			
Par 13, Day 59, Social Functioning	-12.5			

Par 13, Day 59, Role emotional	0			
Par 13, Day 59, Mental health	-25			
Par 13, Day 59, Physical Component Summary	2.16			
Par 13, Day 59, Mental Component Summary	-7.59			
Par 14, Day 57, Physical Functioning	99999			
Par 14, Day 57, Role Physical	99999			
Par 14, Day 57, Bodily Pain	99999			
Par 14, Day 57, General health	99999			
Par 14, Day 57, Vitality	99999			
Par 14, Day 57, Social Functioning	99999			
Par 14, Day 57, Role emotional	99999			
Par 14, Day 57, Mental health	99999			
Par 14, Day 57, Physical Component Summary	99999			
Par 14, Day 57, Mental Component Summary	99999			
Par 15, Day 169, Physical Functioning	99999			
Par 15, Day 169, Role Physical	99999			
Par 15, Day 169, Bodily Pain	99999			
Par 15, Day 169, General health	99999			
Par 15, Day 169, Vitality	99999			
Par 15, Day 169, Social Functioning	99999			
Par 15, Day 169, Role emotional	99999			
Par 15, Day 169, Mental health	99999			
Par 15, Day 169, Physical Component Summary	99999			
Par 15, Day 169, Mental Component Summary	99999			
Par 16, Week 12, Physical Functioning	99999			
Par 16, Week 12, Role Physical	99999			
Par 16, Week 12, Bodily Pain	99999			
Par 16, Week 12, General health	99999			
Par 16, Week 12, Vitality	99999			
Par 16, Week 12, Social Functioning	99999			
Par 16, Week 12, Role emotional	99999			
Par 16, Week 12, Mental health	99999			
Par 16, Week 12, Physical Component Summary	99999			
Par 16, Week 12, Mental Component Summary	99999			
Par 16, Day 112, Physical Functioning	99999			
Par 16, Day 112, Role Physical	99999			
Par 16, Day 112, Bodily Pain	99999			
Par 16, Day 112, General health	99999			
Par 16, Day 112, Vitality	99999			
Par 16, Day 112, Social Functioning	99999			
Par 16, Day 112, Role emotional	99999			
Par 16, Day 112, Mental health	99999			
Par 16, Day 112, Physical Component Summary	99999			
Par 16, Day 112, Mental Component Summary	99999			
Par 17, Day 85, Physical Functioning	99999			

Par 17, Day 85, Role Physical	99999			
Par 17, Day 85, Bodily Pain	99999			
Par 17, Day 85, General health	99999			
Par 17, Day 85, Vitality	99999			
Par 17, Day 85, Social Functioning	99999			
Par 17, Day 85, Role emotional	99999			
Par 17, Day 85, Mental health	99999			
Par 17, Day 85, Physical Component Summary	99999			
Par 17, Day 85, Mental Component Summary	99999			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in EQ-5D-5L Index score over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in EQ-5D-5L Index score over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B
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End point description:

EQ-5D essentially consists of 2 elements: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The EQ-5D descriptive system comprised of the following 5 dimensions: 1.Mobility, 2.Self-Care, 3.Usual Activities, 4.Pain/Discomfort and 5.Anxiety/Depression. Each of these 5 dimensions has 5 levels: 1: no; 2: slight 3: moderate and 4: severe problems; 5: Unable to do. The digits for each of the 5 dimensions were combined in a 5-digit number describing the participant's health state: e.g. state 11111 indicates no problem on any of the 5 dimensions, while state 12345 indicates no problems with Mobility, slight problems with Self-Care, moderate problems with doing Usual Activities, severe Pain or Discomfort and extreme Anxiety or Depression. Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Day 0) and Day 85, Day 87, Day 91, Day 113, Day 162, Day 339, Day 344, Week 12 and Week24

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Scores on scale				
number (not applicable)				
Par 1, Week 12	-0.127	99999	99999	99999
Par 1, Week 24	-0.098	99999	99999	99999
Par 1, Day 339	-0.070	99999	99999	99999
Par 2, Week 12	0.204	99999	99999	99999
Par 2, Week 24	0.041	99999	99999	99999
Par 2, Day 344	0.110	99999	99999	99999

Par 3, Day 113	99999	99999	0.000	99999
Par 4, Week 12	99999	0.097	99999	99999
Par 5, Week 12	99999	99999	99999	0.028
Par 5, Day 162	99999	99999	99999	0.028
Par 6, Day 91	99999	99999	99999	0.000
Par 7, Day 85	99999	99999	99999	99999
Par 8, Day 87	99999	99999	99999	99999

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Scores on scale				
number (not applicable)				
Par 1, Week 12	99999			
Par 1, Week 24	99999			
Par 1, Day 339	99999			
Par 2, Week 12	99999			
Par 2, Week 24	99999			
Par 2, Day 344	99999			
Par 3, Day 113	99999			
Par 4, Week 12	99999			
Par 5, Week 12	99999			
Par 5, Day 162	99999			
Par 6, Day 91	99999			
Par 7, Day 85	0.000			
Par 8, Day 87	0.012			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in EQ-5D-5L Index score over time for participants who never received 100mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in EQ-5D-5L Index score over time for participants who never received 100mg OL Sirukumab in Part B
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End point description:

EQ-5D essentially consists of 2 elements: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The EQ-5D descriptive system comprised of 5 dimensions: 1.Mobility, 2.Self-Care, 3.Usual Activities, 4.Pain/Discomfort and 5.Anxiety/Depression. Each of these 5 dimensions has 5 levels: 1: no problems; 2: slight problems; 3: moderate problems; 4: severe problems; 5: Unable to do. The digits for each of the 5 dimensions were combined in a 5-digit number describing the participant's health state: e.g. state 11111 indicates no problem on any of the 5 dimensions, while state 12345 indicates no problems with Mobility, slight problems with Self-Care, moderate problems with doing Usual Activities, severe Pain or Discomfort and extreme Anxiety or Depression. Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Participants with post baseline data were reported.

End point type	Secondary
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End point timeframe:

Baseline (Day 0) and Day 29, 30, 57, 59, 64, 65, 85, 112, 113,163,169 and 373, Week 12

End point values	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30	99999	-0.248	99999	99999
Par 2, Day 29	99999	0.000	99999	99999
Par 3, Day 29	99999	0.233	99999	99999
Par 4, Week 12	99999	0.000	99999	99999
Par 4, Day 113	99999	0.000	99999	99999
Par 5, Day 85	99999	-0.015	99999	99999
Par 6, Day 65	99999	0.163	99999	99999
Par 7, Week 12	99999	99999	0.163	99999
Par 7, Day 373	99999	99999	0.163	99999
Par 8, Day 64	99999	99999	-0.016	99999
Par 9, Day 29	99999	99999	0.212	99999
Par 10, Day 57	99999	99999	0.000	99999
Par 11, Week 12	99999	99999	99999	-0.069
Par 11, Day 163	99999	99999	99999	0.042
Par 12, Day 85	99999	99999	99999	-0.059
Par 13, Day 59	99999	99999	99999	0.000
Par 14, Day 57	99999	99999	99999	99999
Par 16, Day 169	99999	99999	99999	99999
Par 17,Week 12	0.163	99999	99999	99999
Par 17, Day 112	0.163	99999	99999	99999
Par 18, Day 85	-0.042	99999	99999	99999

End point values	PartB:Placebo SC q2w + 6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30	99999			
Par 2, Day 29	99999			
Par 3, Day 29	99999			
Par 4, Week 12	99999			
Par 4, Day 113	99999			
Par 5, Day 85	99999			
Par 6, Day 65	99999			

Par 7, Week 12	99999			
Par 7, Day 373	99999			
Par 8, Day 64	99999			
Par 9, Day 29	99999			
Par 10, Day 57	99999			
Par 11, Week 12	99999			
Par 11, Day 163	99999			
Par 12, Day 85	99999			
Par 13, Day 59	99999			
Par 14, Day 57	0.000			
Par 16, Day 169	0.232			
Par 17, Week 12	99999			
Par 17, Day 112	99999			
Par 18, Day 85	99999			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in FACIT-Fatigue scores over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in FACIT-Fatigue scores over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B
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End point description:

The FACIT-Fatigue is a 13-item questionnaire formatted for self-administration that assesses participant reported fatigue and its impact upon daily activities and function over the past seven days. Participants were asked to answer each question using a 5-point Likert-type scale (4 = Not at all; 3 = A little bit; 2 = Somewhat; 1 = Quite a bit; and 0 = Very Much) where 0 is a bad response and 4 is good response. Each of the 13 items of the FACIT-Fatigue Scale ranges from 0-4, with a range of possible total score from 0-52, 0 (Extreme fatigue) to 52 (No fatigue) where 0 being the worst possible score and 52 the best (i.e. less fatigue). Scores below 30 indicate severe fatigue. Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Day 0) and Day 85,87,91,113,162, 344,339,Week 12, 24

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Scores on scale				
number (not applicable)				
Par 1, Week 12, I Feel Fatigued	-3	99999	99999	99999
Par 1, Week 24, I Feel Fatigued	-4	99999	99999	99999
Par 1, Day 339, I Feel Fatigued	3	99999	99999	99999
Par 2, Week 12, I Feel Fatigued	8	99999	99999	99999

Par 2, Week 24, I Feel Fatigued	2	99999	99999	99999
Par 2, Day 344, I Feel Fatigued	6	99999	99999	99999
Par 3, Day 113, I Feel Fatigued	99999	99999	2	99999
Par 4, Week 12, I Feel Fatigued	99999	2	99999	99999
Par 5, Week 12, I Feel Fatigued	99999	99999	99999	-5
Par 5, Day 162, I Feel Fatigued	99999	99999	99999	-4
Par 6, Day 91, I Feel Fatigued	99999	99999	99999	-12
Par 7, Day 85, I Feel Fatigued	99999	99999	99999	99999
Par 8, Day 87, I Feel Fatigued	99999	99999	99999	99999

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Scores on scale				
number (not applicable)				
Par 1, Week 12, I Feel Fatigued	99999			
Par 1, Week 24, I Feel Fatigued	99999			
Par 1, Day 339, I Feel Fatigued	99999			
Par 2, Week 12, I Feel Fatigued	99999			
Par 2, Week 24, I Feel Fatigued	99999			
Par 2, Day 344, I Feel Fatigued	99999			
Par 3, Day 113, I Feel Fatigued	99999			
Par 4, Week 12, I Feel Fatigued	99999			
Par 5, Week 12, I Feel Fatigued	99999			
Par 5, Day 162, I Feel Fatigued	99999			
Par 6, Day 91, I Feel Fatigued	99999			
Par 7, Day 85, I Feel Fatigued	-7			
Par 8, Day 87, I Feel Fatigued	-10			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in FACIT-Fatigue scores over time for participants who never received 100mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in FACIT-Fatigue scores over time for participants who never received 100mg OL Sirukumab in Part B
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End point description:

The FACIT-Fatigue is a 13-item questionnaire formatted for self-administration that assesses participant reported fatigue and its impact upon daily activities and function over the past seven days. Participants were asked to answer each question using a 5-point Likert-type scale (4 = Not at all; 3 = A little bit; 2 = Somewhat; 1 = Quite a bit; and 0 = Very Much) where 0 is a bad response and 4 is good response. Each of the 13 items of the FACIT-Fatigue Scale ranges from 0-4, with a range of possible total score from 0-52, 0 (Extreme fatigue) to 52 (No fatigue) where 0 being the worst possible score and 52 the best (i.e. less fatigue). Scores below 30 indicate severe fatigue. Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-

Baseline value minus Baseline value. Participants with post baseline data were reported.

End point type	Secondary
End point timeframe:	
Baseline (Day 0) and Day 85,87,91,113,162 344,339,Week 12, 24	

End point values	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30, I Feel Fatigued	99999	-3	99999	99999
Par 2, Day 29, I Feel Fatigued	99999	-1	99999	99999
Par 3, Day 23, I Feel Fatigued	99999	0	99999	99999
Par 4, Week 12, I Feel Fatigued	99999	2	99999	99999
Par 4, Day 113, I Feel Fatigued	99999	-16	99999	99999
Par 5, Week 8, I Feel Fatigued	99999	-1	99999	99999
Par 5, Day 85, I Feel Fatigued	99999	-3	99999	99999
Par 6, Day 65, I Feel Fatigued	99999	-1	99999	99999
Par 7, Week 12, I Feel Fatigued	99999	99999	0	99999
Par 7, Day 373, I Feel Fatigued	99999	99999	5	99999
Par 8, Day 64, I Feel Fatigued	99999	99999	-3	99999
Par 9, Day 29, I Feel Fatigued	99999	99999	0	99999
Par 10, Day 57, I Feel Fatigued	99999	99999	13	99999
Par 11, Week 12, I Feel Fatigued	99999	99999	99999	5
Par 11, Day 163, I Feel Fatigued	99999	99999	99999	6
Par 12, Day 85, I Feel Fatigued	99999	99999	99999	-1
Par 13, Day 59, I Feel Fatigued	99999	99999	99999	7
Par 14, Day 57, I Feel Fatigued	99999	99999	99999	99999
Par 16, Day 169, I Feel Fatigued	99999	99999	99999	99999
Par 17, Week 12, I Feel Fatigued	6	99999	99999	99999
Par 17, Day112, I Feel Fatigued	6	99999	99999	99999
Par 18, Day 85, I Feel Fatigued	-1	99999	99999	99999

End point values	PartB:Placebo SC q2w + 6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30, I Feel Fatigued	99999			
Par 2, Day 29, I Feel Fatigued	99999			
Par 3, Day 23, I Feel Fatigued	99999			
Par 4, Week 12, I Feel Fatigued	99999			

Par 4, Day 113, I Feel Fatigued	99999			
Par 5, Week 8, I Feel Fatigued	99999			
Par 5, Day 85, I Feel Fatigued	99999			
Par 6, Day 65, I Feel Fatigued	99999			
Par 7, Week 12, I Feel Fatigued	99999			
Par 7, Day 373, I Feel Fatigued	99999			
Par 8, Day 64, I Feel Fatigued	99999			
Par 9, Day 29, I Feel Fatigued	99999			
Par 10, Day 57, I Feel Fatigued	99999			
Par 11, Week 12, I Feel Fatigued	99999			
Par 11, Day 163, I Feel Fatigued	99999			
Par 12, Day 85, I Feel Fatigued	99999			
Par 13, Day 59, I Feel Fatigued	99999			
Par 14, Day 57, I Feel Fatigued	-11			
Par 16, Day 169, I Feel Fatigued	0			
Par 17, Week 12, I Feel Fatigued	99999			
Par 17, Day112, I Feel Fatigued	99999			
Par 18, Day 85, I Feel Fatigued	99999			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in Pain NRS scores over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in Pain NRS scores over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B
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End point description:

The assessment of pain severity was made using a single pain severity item on which participants were asked to rate the severity of their average pain now on an 11-point numeric rating scale ranging from 0, "no pain" to 10, "the worst pain imaginable". Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Day 0) and Day 85,87,91,113,162 344,339,Week 12, 24

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Scores on scale				
number (not applicable)				
Par 1, Week 2	4	99999	99999	99999
Par 1, Week 4	-1	99999	99999	99999
Par 1, Week 8	-1	99999	99999	99999

Par 1, Week 12	4	99999	99999	99999
Par 1, Week 24	0	99999	99999	99999
Par 1, Day 339	-2	99999	99999	99999
Par 2, Week 4	0	99999	99999	99999
Par 2, Week 8	0	99999	99999	99999
Par 2, Week 12	1	99999	0	99999
Par 2, Week 24	0	99999	99999	99999
Par 2, Week 38	1	99999	99999	99999
Par 2, Week 40	1	99999	99999	99999
Par 2, Day 344	0	99999	99999	99999
Par 3, Day 113	99999	99999	-2	99999
Par 4, Week 4	99999	-2	99999	99999
Par 4, Week 8	99999	0	99999	99999
Par 4, Week 12	99999	-3	99999	99999
Par 5, Week 4	99999	99999	99999	0
Par 5, Week 8	99999	99999	99999	1
Par 5, Week 12	99999	99999	99999	0
Par 5, Week 14	99999	99999	99999	1
Par 5, Week 16	99999	99999	99999	0
Par 5, Day 162	99999	99999	99999	1
Par 6, Week 2	99999	99999	99999	2
Par 6, Week 4	99999	99999	99999	-2
Par 6, Week 8	99999	99999	99999	-2
Par 6, Day 91	99999	99999	99999	-1
Par 7, Week 2	99999	99999	99999	99999
Par 7, Week 4	99999	99999	99999	99999
Par 7, Week 8	99999	99999	99999	99999
Par 7, Day 85	99999	99999	99999	99999
Par 8, Week 2	99999	99999	99999	99999
Par 8, Week 4	99999	99999	99999	99999
Par 8, Day 87	99999	99999	99999	99999

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Scores on scale				
number (not applicable)				
Par 1, Week 2	99999			
Par 1, Week 4	99999			
Par 1, Week 8	99999			
Par 1, Week 12	99999			
Par 1, Week 24	99999			
Par 1, Day 339	99999			
Par 2, Week 4	99999			
Par 2, Week 8	99999			
Par 2, Week 12	99999			
Par 2, Week 24	99999			

Par 2, Week 38	99999			
Par 2, Week 40	99999			
Par 2, Day 344	99999			
Par 3, Day 113	99999			
Par 4, Week 4	99999			
Par 4, Week 8	99999			
Par 4, Week 12	99999			
Par 5, Week 4	99999			
Par 5, Week 8	99999			
Par 5, Week 12	99999			
Par 5, Week 14	99999			
Par 5, Week 16	99999			
Par 5, Day 162	99999			
Par 6, Week 2	99999			
Par 6, Week 4	99999			
Par 6, Week 8	99999			
Par 6, Day 91	99999			
Par 7, Week 2	-1			
Par 7, Week 4	0			
Par 7, Week 8	1			
Par 7, Day 85	0			
Par 8, Week 2	2			
Par 8, Week 4	0			
Par 8, Day 87	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in Pain NRS scores over time for participants who never received at least one dose of 100mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in Pain NRS scores over time for participants who never received at least one dose of 100mg OL Sirukumab in Part B
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End point description:

The assessment of pain severity was made using a single pain severity item on which participants were asked to rate the severity of their average pain now on an 11-point numeric rating scale ranging from 0, "no pain" to 10, "the worst pain imaginable". Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Participants with post baseline data were reported.

End point type	Secondary
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End point timeframe:

Baseline (Day 0) and Day 85,87,91,113,162 344,339,Week 12, 24

End point values	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30	99999	0	99999	99999
Par 2, Day 29	99999	0	99999	99999
Par 3, Day 23	99999	-1	99999	99999
Par 4, Week 4	99999	0	99999	99999
Par 4, Week 8	99999	0	99999	99999
Par 4, Week 12	99999	0	99999	99999
Par 4, Day 113	99999	0	99999	99999
Par 5, Week 4	99999	0	99999	99999
Par 5, Week 8	99999	0	99999	99999
Par 5, Day 85	99999	2	99999	99999
Par 6, Week 4	99999	0	99999	99999
Par 6, Day 65	99999	0	99999	99999
Par 7, Week 4	99999	99999	1	99999
Par 7, Week 8	99999	99999	0	99999
Par 7, Week 12	99999	99999	0	99999
Par 7, Day 373	99999	99999	0	99999
Par 8, Week 4	99999	99999	0	99999
Par 8, Day 64	99999	99999	-1	99999
Par 9, Day 29	99999	99999	0	99999
Par 10, Week 4	99999	99999	0	99999
Par 10, Day 57	99999	99999	-1	99999
Par 11, Week 4	99999	99999	99999	0
Par 11, Week 8	99999	99999	99999	0
Par 11, Week 12	99999	99999	99999	1
Par 11, Day 163	99999	99999	99999	1
Par 12, Week 4	99999	99999	99999	0
Par 12, Week 8	99999	99999	99999	-1
Par 12, Day 85	99999	99999	99999	0
Par 13, Week 4	99999	99999	99999	0
Par 13, Day 59	99999	99999	99999	0
Par 14, Week 4	99999	99999	99999	99999
Par 14, Day 57	99999	99999	99999	99999
Par 16, Day 169	99999	99999	99999	99999
Par 17, Week 4	-2	99999	99999	99999
Par 17, Week 12	-2	99999	99999	99999
Par 17, Day 112	-2	99999	99999	99999
Par 18, Week 8	1	99999	99999	99999
Par 18, Day 85	0	99999	99999	99999

End point values	PartB:Placebo SC q2w + 6 month prednisone			
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Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30	99999			
Par 2, Day 29	99999			
Par 3, Day 23	99999			
Par 4, Week 4	99999			
Par 4, Week 8	99999			
Par 4, Week 12	99999			
Par 4, Day 113	99999			
Par 5, Week 4	99999			
Par 5, Week 8	99999			
Par 5, Day 85	99999			
Par 6, Week 4	99999			
Par 6, Day 65	99999			
Par 7, Week 4	99999			
Par 7, Week 8	99999			
Par 7, Week 12	99999			
Par 7, Day 373	99999			
Par 8, Week 4	99999			
Par 8, Day 64	99999			
Par 9, Day 29	99999			
Par 10, Week 4	99999			
Par 10, Day 57	99999			
Par 11, Week 4	99999			
Par 11, Week 8	99999			
Par 11, Week 12	99999			
Par 11, Day 163	99999			
Par 12, Week 4	99999			
Par 12, Week 8	99999			
Par 12, Day 85	99999			
Par 13, Week 4	99999			
Par 13, Day 59	99999			
Par 14, Week 4	0			
Par 14, Day 57	-1			
Par 16, Day 169	-3			
Par 17, Week 4	99999			
Par 17, Week 12	99999			
Par 17, Day 112	99999			
Par 18, Week 8	99999			
Par 18, Day 85	99999			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: HAQDI Score over Time for participants who received at least one Dose of 100 mg OL Sirukumab in Part B

End point title	Part B: HAQDI Score over Time for participants who received at least one Dose of 100 mg OL Sirukumab in Part B
End point description:	
<p>The HAQ-DI indicates the extent of the participant's functional ability during the past week, and was assessed for the subgroup of participants with symptoms of Polymyalgia Rheumatic (PMR). The HAQ-DI included 20 questions in 8 categories of functioning – dressing and grooming, arising, eating, walking, hygiene, reach, grip, and usual activities. Each functional area contains at least two questions. For each question, there is a 4-level difficulty scale that is scored from 0 to 3, representing “no difficulty” (0), “some difficulty” (1), “much difficulty” (2), and “unable to do” (3) where higher scores indicating worse disability. The functional areas assessed were: activities, arising, dressing and grooming, eating, grip, hygiene, reach and walking. The score for each of the 8 category scores is taken as the maximum score given to the related questions. If no questions within a given functional area were answered, no score was provided for that category.</p>	
End point type	Secondary
End point timeframe:	
Day 87, 339, 344, Week 12, 24	

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:Placebo SC q2w + 6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	0 ^[23]	0 ^[24]
Units: Scores on scale				
number (not applicable)				
Par 1, Week 12, Able to Do Chores	1	99999		
Par 1, Week 12, Get In and Out of a car	0	99999		
Par 1, Week 12, Run Errands and Shop	0	99999		
Par 1, Week 12, Get In and Out of Bed	0	99999		
Par 1, Week 12, Stand Up From a Straight	1	99999		
Par 1, Week 12, Dress yourself	1	99999		
Par 1, Week 12, Shampoo your hair	0	99999		
Par 1, Week 12, Cut your meat	0	99999		
Par 1, Week 12, Lift a Full Cup/Glass to mouth	0	99999		
Par 1, Week 12, Open a New Milk Carton	1	99999		
Par 1, Week 12, Open car doors	0	99999		
Par 1, Week 12, Open Jars Previously Opened	1	99999		
Par 1, Week 12, Turn Faucets On And Off	1	99999		
Par 1, Week 12, Get On and Off The Toilet	0	99999		
Par 1, Week 12, Take a Tub Bath	3	99999		
Par 1, Week 12, Wash and Dry Your Body	0	99999		
Par 1, Week 12, Bend Down Pick Up Clothing-Floor	1	99999		
Par 1, Week 12, Reach-Get Down 5 Lb Obj Above Head	1	99999		
Par 1, Week 12, Climb Up Five Steps	0	99999		
Par 1, Week 12, Walk Outdoors on Flat Ground	0	99999		
Par 1, Week 24, Able to Do Chores	0	99999		

Par 1, Week 24, Get In and Out of a car	0	99999		
Par 1, Week 24, Run Errands and Shop	0	99999		
Par 1, Week 24, Get In and Out of Bed	0	99999		
Par 1, Week 24, Stand Up From a Straight	0	99999		
Par 1, Week 24, Dress yourself	0	99999		
Par 1, Week 24, Shampoo your hair	0	99999		
Par 1, Week 24, Cut your meat	0	99999		
Par 1, Week 24, Lift a Full Cup/Glass to mouth	0	99999		
Par 1, Week 24, Open a New Milk Carton	0	99999		
Par 1, Week 24, Open car doors	0	99999		
Par 1, Week 24, Open Jars Previously Opened	1	99999		
Par 1, Week 24, Turn Faucets On And Off	1	99999		
Par 1, Week 24, Get On and Off The Toilet	0	99999		
Par 1, Week 24, Take a Tub Bath	3	99999		
Par 1, Week 24, Wash and Dry Your Body	0	99999		
Par 1, Week 24, Bend Down Pick Up Clothing-Floor	0	99999		
Par 1, Week 24, Reach-Get Down 5 Lb Obj Above Head	0	99999		
Par 1, Week 24, Climb Up Five Steps	0	99999		
Par 1, Week 24, Walk Outdoors on Flat Ground	0	99999		
Par 1, Day 339, Able to Do Chores	0	99999		
Par 1, Day 339, Get In and Out of a car	0	99999		
Par 1, Day 339, Run Errands and Shop	0	99999		
Par 1, Day 339, Get In and Out of Bed	0	99999		
Par 1, Day 339, Stand Up From a Straight	0	99999		
Par 1, Day 339, Dress yourself	0	99999		
Par 1, Day 339, Shampoo your hair	0	99999		
Par 1, Day 339, Cut your meat	0	99999		
Par 1, Day 339, Lift a Full Cup/Glass to mouth	0	99999		
Par 1, Day 339, Open a New Milk Carton	1	99999		
Par 1, Day 339, Open car doors	0	99999		
Par 1, Day 339, Open Jars Previously Opened	0	99999		
Par 1, Day 339, Turn Faucets On And Off	0	99999		
Par 1, Day 339, Get On and Off The Toilet	0	99999		
Par 1, Day 339, Take a Tub Bath	3	99999		
Par 1, Day 339, Wash and Dry Your Body	0	99999		
Par 1, Day 339, Bend Down Pick Up Clothing-Floor	0	99999		
Par 1, Day 339, Reach-Get Down 5 Lb Obj Above Head	0	99999		
Par 1, Day 339, Climb Up Five Steps	0	99999		
Par 1, Day 339, Walk Outdoors on Flat Ground	0	99999		

Par 2, Week 12, Able to Do Chores	1	99999		
Par 2, Week 12, Get In and Out of a car	0	99999		
Par 2, Week 12, Run Errands and Shop	0	99999		
Par 2, Week 12, Get In and Out of Bed	0	99999		
Par 2, Week 12, Stand Up From a Straight	0	99999		
Par 2, Week 12, Dress yourself	0	99999		
Par 2, Week 12, Shampoo your hair	0	99999		
Par 2, Week 12, Cut your meat	0	99999		
Par 2, Week 12, Lift a Full Cup/Glass to mouth	0	99999		
Par 2, Week 12, Open a New Milk Carton	1	99999		
Par 2, Week 12, Open car doors	0	99999		
Par 2, Week 12, Open Jars Previously Opened	0	99999		
Par 2, Week 12, Turn Faucets On And Off	0	99999		
Par 2, Week 12, Get On and Off The Toilet	0	99999		
Par 2, Week 12, Take a Tub Bath	3	99999		
Par 2, Week 12, Wash and Dry Your Body	0	99999		
Par 2, Week 12, Bend Down Pick Up Clothing-Floor	1	99999		
Par 2, Week 12, Reach-Get Down 5 Lb Obj Above Head	2	99999		
Par 2, Week 12, Climb Up Five Steps	0	99999		
Par 2, Week 12, Walk Outdoors on Flat Ground	0	99999		
Par 2, Week 24, Able to Do Chores	0	99999		
Par 2, Week 24, Get In and Out of a car	0	99999		
Par 2, Week 24, Run Errands and Shop	0	99999		
Par 2, Week 24, Get In and Out of Bed	0	99999		
Par 2, Week 24, Stand Up From a Straight	0	99999		
Par 2, Week 24, Dress yourself	0	99999		
Par 2, Week 24, Shampoo your hair	0	99999		
Par 2, Week 24, Cut your meat	0	99999		
Par 2, Week 24, Lift a Full Cup/Glass to mouth	0	99999		
Par 2, Week 24, Open a New Milk Carton	0	99999		
Par 2, Week 24, Open car doors	0	99999		
Par 2, Week 24, Open Jars Previously Opened	0	99999		
Par 2, Week 24, Turn Faucets On And Off	0	99999		
Par 2, Week 24, Get On and Off The Toilet	0	99999		
Par 2, Week 24, Take a Tub Bath	0	99999		
Par 2, Week 24, Wash and Dry Your Body	0	99999		
Par 2, Week 24, Bend Down Pick Up Clothing-Floor	0	99999		
Par 2, Week 24, Reach-Get Down 5 Lb Obj Above Head	1	99999		
Par 2, Week 24, Climb Up Five Steps	0	99999		

Par 2, Week 24, Walk Outdoors on Flat Ground	0	99999		
Par 2, Day 344, Able to Do Chores	1	99999		
Par 2, Day 344, Get In and Out of a car	0	99999		
Par 2, Day 344, Run Errands and Shop	0	99999		
Par 2, Day 344, Get In and Out of Bed	0	99999		
Par 2, Day 344, Stand Up From a Straight	0	99999		
Par 2, Day 344, Dress yourself	0	99999		
Par 2, Day 344, Shampoo your hair	0	99999		
Par 2, Day 344, Cut your meat	0	99999		
Par 2, Day 344, Lift a Full Cup/Glass to mouth	0	99999		
Par 2, Day 344, Open a New Milk Carton	1	99999		
Par 2, Day 344, Open car doors	0	99999		
Par 2, Day 344, Open Jars Previously Opened	0	99999		
Par 2, Day 344, Turn Faucets On And Off	0	99999		
Par 2, Day 344, Get On and Off The Toilet	0	99999		
Par 2, Day 344, Take a Tub Bath	3	99999		
Par 2, Day 344, Wash and Dry Your Body	0	99999		
Par 2, Day 344, Bend Down Pick Up Clothing-Floor	0	99999		
Par 2, Day 344, Reach-Get Down 5 Lb Obj Above Head	1	99999		
Par 2, Day 344, Climb Up Five Steps	0	99999		
Par 2, Day 344, Walk Outdoors on Flat Ground	0	99999		
Par 3, Week 12, Able to Do Chores	99999	0		
Par 3, Week 12, Get In and Out of a car	99999	0		
Par 3, Week 12, Run Errands and Shop	99999	0		
Par 3, Week 12, Get In and Out of Bed	99999	0		
Par 3, Week 12, Stand Up From a Straight	99999	0		
Par 3, Week 12, Dress yourself	99999	0		
Par 3, Week 12, Shampoo your hair	99999	0		
Par 3, Week 12, Cut your meat	99999	0		
Par 3, Week 12, Lift a Full Cup/Glass to mouth	99999	0		
Par 3, Week 12, Open a New Milk Carton	99999	0		
Par 3, Week 12, Open car doors	99999	0		
Par 3, Week 12, Open Jars Previously Opened	99999	0		
Par 3, Week 12, Turn Faucets On And Off	99999	0		
Par 3, Week 12, Get On and Off The Toilet	99999	0		
Par 3, Week 12, Take a Tub Bath	99999	0		
Par 3, Week 12, Wash and Dry Your Body	99999	0		
Par 3, Week 12, Bend Down Pick Up Clothing-Floor	99999	0		
Par 3, Week 12, Reach-Get Down 5 Lb Obj Above Head	99999	0		

Par 3, Week 12, Climb Up Five Steps	99999	0		
Par 3, Week 12, Walk Outdoors on Flat Ground	99999	0		
Par 4, Day 87, Able to Do Chores	99999	99999		
Par 4, Day 87, Get In and Out of a car	99999	99999		
Par 4, Day 87, Run Errands and Shop	99999	99999		
Par 4, Day 87, Get In and Out of Bed	99999	99999		
Par 4, Day 87, Stand Up From a Straight	99999	99999		
Par 4, Day 87, Dress yourself	99999	99999		
Par 4, Day 87, Shampoo your hair	99999	99999		
Par 4, Day 87, Cut your meat	99999	99999		
Par 4, Day 87, Lift a Full Cup/Glass to mouth	99999	99999		
Par 4, Day 87, Open a New Milk Carton	99999	99999		
Par 4, Day 87, Open Jars Previously Opened	99999	99999		
Par 4, Day 87, Turn Faucets On And Off	99999	99999		
Par 4, Day 87, Get On and Off The Toilet	99999	99999		
Par 4, Day 87, Take a Tub Bath	99999	99999		
Par 4, Day 87, Wash and Dry Your Body	99999	99999		
Par 4, Day 87, Bend Down Pick Up Clothing-Floor	99999	99999		
Par 4, Day 87, Reach-Get Down 5 Lb Obj Above Head	99999	99999		
Par 4, Day 87, Climb Up Five Steps	99999	99999		
Par 4, Day 87, Walk Outdoors on Flat Ground	99999	99999		

Notes:

[23] - Data for number of participants in sustained remission over time for Part B is presented.

[24] - Data for number of participants in sustained remission over time for Part B is presented.

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	1 ^[25]			
Units: Scores on scale				
number (not applicable)				
Par 1, Week 12, Able to Do Chores	99999			
Par 1, Week 12, Get In and Out of a car	99999			
Par 1, Week 12, Run Errands and Shop	99999			
Par 1, Week 12, Get In and Out of Bed	99999			
Par 1, Week 12, Stand Up From a Straight	99999			
Par 1, Week 12, Dress yourself	99999			
Par 1, Week 12, Shampoo your hair	99999			
Par 1, Week 12, Cut your meat	99999			
Par 1, Week 12, Lift a Full Cup/Glass to mouth	99999			
Par 1, Week 12, Open a New Milk Carton	99999			
Par 1, Week 12, Open car doors	99999			
Par 1, Week 12, Open Jars Previously Opened	99999			

Par 1, Week 12, Turn Faucets On And Off	99999			
Par 1, Week 12, Get On and Off The Toilet	99999			
Par 1, Week 12, Take a Tub Bath	99999			
Par 1, Week 12, Wash and Dry Your Body	99999			
Par 1, Week 12, Bend Down Pick Up Clothing-Floor	99999			
Par 1, Week 12, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 1, Week 12, Climb Up Five Steps	99999			
Par 1, Week 12, Walk Outdoors on Flat Ground	99999			
Par 1, Week 24, Able to Do Chores	99999			
Par 1, Week 24, Get In and Out of a car	99999			
Par 1, Week 24, Run Errands and Shop	99999			
Par 1, Week 24, Get In and Out of Bed	99999			
Par 1, Week 24, Stand Up From a Straight	99999			
Par 1, Week 24, Dress yourself	99999			
Par 1, Week 24, Shampoo your hair	99999			
Par 1, Week 24, Cut your meat	99999			
Par 1, Week 24, Lift a Full Cup/Glass to mouth	99999			
Par 1, Week 24, Open a New Milk Carton	99999			
Par 1, Week 24, Open car doors	99999			
Par 1, Week 24, Open Jars Previously Opened	99999			
Par 1, Week 24, Turn Faucets On And Off	99999			
Par 1, Week 24, Get On and Off The Toilet	99999			
Par 1, Week 24, Take a Tub Bath	99999			
Par 1, Week 24, Wash and Dry Your Body	99999			
Par 1, Week 24, Bend Down Pick Up Clothing-Floor	99999			
Par 1, Week 24, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 1, Week 24, Climb Up Five Steps	99999			
Par 1, Week 24, Walk Outdoors on Flat Ground	99999			
Par 1, Day 339, Able to Do Chores	99999			
Par 1, Day 339, Get In and Out of a car	99999			
Par 1, Day 339, Run Errands and Shop	99999			
Par 1, Day 339, Get In and Out of Bed	99999			
Par 1, Day 339, Stand Up From a Straight	99999			
Par 1, Day 339, Dress yourself	99999			
Par 1, Day 339, Shampoo your hair	99999			
Par 1, Day 339, Cut your meat	99999			
Par 1, Day 339, Lift a Full Cup/Glass to mouth	99999			
Par 1, Day 339, Open a New Milk Carton	99999			
Par 1, Day 339, Open car doors	99999			

Par 1, Day 339, Open Jars Previously Opened	99999			
Par 1, Day 339, Turn Faucets On And Off	99999			
Par 1, Day 339, Get On and Off The Toilet	99999			
Par 1, Day 339, Take a Tub Bath	99999			
Par 1, Day 339, Wash and Dry Your Body	99999			
Par 1, Day 339, Bend Down Pick Up Clothing-Floor	99999			
Par 1, Day 339, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 1, Day 339, Climb Up Five Steps	99999			
Par 1, Day 339, Walk Outdoors on Flat Ground	99999			
Par 2, Week 12, Able to Do Chores	99999			
Par 2, Week 12, Get In and Out of a car	99999			
Par 2, Week 12, Run Errands and Shop	99999			
Par 2, Week 12, Get In and Out of Bed	99999			
Par 2, Week 12, Stand Up From a Straight	99999			
Par 2, Week 12, Dress yourself	99999			
Par 2, Week 12, Shampoo your hair	99999			
Par 2, Week 12, Cut your meat	99999			
Par 2, Week 12, Lift a Full Cup/Glass to mouth	99999			
Par 2, Week 12, Open a New Milk Carton	99999			
Par 2, Week 12, Open car doors	99999			
Par 2, Week 12, Open Jars Previously Opened	99999			
Par 2, Week 12, Turn Faucets On And Off	99999			
Par 2, Week 12, Get On and Off The Toilet	99999			
Par 2, Week 12, Take a Tub Bath	99999			
Par 2, Week 12, Wash and Dry Your Body	99999			
Par 2, Week 12, Bend Down Pick Up Clothing-Floor	99999			
Par 2, Week 12, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 2, Week 12, Climb Up Five Steps	99999			
Par 2, Week 12, Walk Outdoors on Flat Ground	99999			
Par 2, Week 24, Able to Do Chores	99999			
Par 2, Week 24, Get In and Out of a car	99999			
Par 2, Week 24, Run Errands and Shop	99999			
Par 2, Week 24, Get In and Out of Bed	99999			
Par 2, Week 24, Stand Up From a Straight	99999			
Par 2, Week 24, Dress yourself	99999			
Par 2, Week 24, Shampoo your hair	99999			
Par 2, Week 24, Cut your meat	99999			
Par 2, Week 24, Lift a Full Cup/Glass to mouth	99999			

Par 2, Week 24, Open a New Milk Carton	99999			
Par 2, Week 24, Open car doors	99999			
Par 2, Week 24, Open Jars Previously Opened	99999			
Par 2, Week 24, Turn Faucets On And Off	99999			
Par 2, Week 24, Get On and Off The Toilet	99999			
Par 2, Week 24, Take a Tub Bath	99999			
Par 2, Week 24, Wash and Dry Your Body	99999			
Par 2, Week 24, Bend Down Pick Up Clothing-Floor	99999			
Par 2, Week 24, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 2, Week 24, Climb Up Five Steps	99999			
Par 2, Week 24, Walk Outdoors on Flat Ground	99999			
Par 2, Day 344, Able to Do Chores	99999			
Par 2, Day 344, Get In and Out of a car	99999			
Par 2, Day 344, Run Errands and Shop	99999			
Par 2, Day 344, Get In and Out of Bed	99999			
Par 2, Day 344, Stand Up From a Straight	99999			
Par 2, Day 344, Dress yourself	99999			
Par 2, Day 344, Shampoo your hair	99999			
Par 2, Day 344, Cut your meat	99999			
Par 2, Day 344, Lift a Full Cup/Glass to mouth	99999			
Par 2, Day 344, Open a New Milk Carton	99999			
Par 2, Day 344, Open car doors	99999			
Par 2, Day 344, Open Jars Previously Opened	99999			
Par 2, Day 344, Turn Faucets On And Off	99999			
Par 2, Day 344, Get On and Off The Toilet	99999			
Par 2, Day 344, Take a Tub Bath	99999			
Par 2, Day 344, Wash and Dry Your Body	99999			
Par 2, Day 344, Bend Down Pick Up Clothing-Floor	99999			
Par 2, Day 344, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 2, Day 344, Climb Up Five Steps	99999			
Par 2, Day 344, Walk Outdoors on Flat Ground	99999			
Par 3, Week 12, Able to Do Chores	99999			
Par 3, Week 12, Get In and Out of a car	99999			
Par 3, Week 12, Run Errands and Shop	99999			
Par 3, Week 12, Get In and Out of Bed	99999			
Par 3, Week 12, Stand Up From a Straight	99999			
Par 3, Week 12, Dress yourself	99999			
Par 3, Week 12, Shampoo your hair	99999			
Par 3, Week 12, Cut your meat	99999			

Par 3, Week 12, Lift a Full Cup/Glass to mouth	99999			
Par 3, Week 12, Open a New Milk Carton	99999			
Par 3, Week 12, Open car doors	99999			
Par 3, Week 12, Open Jars Previously Opened	99999			
Par 3, Week 12, Turn Faucets On And Off	99999			
Par 3, Week 12, Get On and Off The Toilet	99999			
Par 3, Week 12, Take a Tub Bath	99999			
Par 3, Week 12, Wash and Dry Your Body	99999			
Par 3, Week 12, Bend Down Pick Up Clothing-Floor	99999			
Par 3, Week 12, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 3, Week 12, Climb Up Five Steps	99999			
Par 3, Week 12, Walk Outdoors on Flat Ground	99999			
Par 4, Day 87, Able to Do Chores	1			
Par 4, Day 87, Get In and Out of a car	0			
Par 4, Day 87, Run Errands and Shop	0			
Par 4, Day 87, Get In and Out of Bed	0			
Par 4, Day 87, Stand Up From a Straight	0			
Par 4, Day 87, Dress yourself	0			
Par 4, Day 87, Shampoo your hair	0			
Par 4, Day 87, Cut your meat	0			
Par 4, Day 87, Lift a Full Cup/Glass to mouth	0			
Par 4, Day 87, Open a New Milk Carton	0			
Par 4, Day 87, Open Jars Previously Opened	0			
Par 4, Day 87, Turn Faucets On And Off	0			
Par 4, Day 87, Get On and Off The Toilet	0			
Par 4, Day 87, Take a Tub Bath	0			
Par 4, Day 87, Wash and Dry Your Body	1			
Par 4, Day 87, Bend Down Pick Up Clothing-Floor	0			
Par 4, Day 87, Reach-Get Down 5 Lb Obj Above Head	1			
Par 4, Day 87, Climb Up Five Steps	0			
Par 4, Day 87, Walk Outdoors on Flat Ground	0			

Notes:

[25] - Data for number of participants in sustained remission over time for Part B is presented.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: HAQDI Score over time for participants who never received 100 mg OL Sirukumab in Part B

End point title	Part B: HAQDI Score over time for participants who never received 100 mg OL Sirukumab in Part B
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End point description:

The HAQ-DI indicates the extent of the participant's functional ability during the past week, and was assessed for the subgroup of participants with symptoms of Polymyalgia Rheumatic (PMR). The HAQ-DI included 20 questions in 8 categories of functioning – dressing and grooming, arising, eating, walking, hygiene, reach, grip, and usual activities. Each functional area contains at least two questions. For each question, there is a 4-level difficulty scale that is scored from 0 to 3, representing “no difficulty” (0), “some difficulty” (1), “much difficulty” (2), and “unable to do” (3) where higher scores indicating worse disability. The functional areas assessed were: activities, arising, dressing and grooming, eating, grip, hygiene, reach and walking. The score for each of the 8 category scores is taken as the maximum score given to the related questions. If no questions within a given functional area were answered, no score was provided for that category.

End point type	Secondary
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End point timeframe:

Day 29, 64, 65, 85, 112, 113, 169, 373 and Week 12

End point values	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	3
Units: Scores on scale				
number (not applicable)				
Par 1, Day 29, Able to Do Chores	99999	99999	99999	0
Par 1, Day 29, Get In and Out of a car	99999	99999	99999	0
Par 1, Day 29, Run Errands and Shop	99999	99999	99999	0
Par 1, Day 29, Get In and Out of Bed	99999	99999	99999	0
Par 1, Day 29, Stand Up From a Straight Chair	99999	99999	99999	0
Par 1, Day 29, Dress yourself	99999	99999	99999	0
Par 1, Day 29, Shampoo your hair	99999	99999	99999	0
Par 1, Day 29, Cut your meat	99999	99999	99999	0
Par 1, Day 29, Lift a Full Cup or Glass to Mouth	99999	99999	99999	0
Par 1, Day 29, Open a New Milk Carton	99999	99999	99999	0
Par 1, Day 29, Open car doors	99999	99999	99999	0
Par 1, Day 29, Open Jars Previously Opened	99999	99999	99999	0
Par 1, Day 29, Turn Faucets On And Off	99999	99999	99999	0
Par 1, Day 29, Get On and Off The Toilet	99999	99999	99999	0
Par 1, Day 29, Take a Tub Bath	99999	99999	99999	0
Par 1, Day 29, Wash and Dry Your Body	99999	99999	99999	0
Par 1, Day 29, Bend Down Pick Up Clothing- Floor	99999	99999	99999	0
Par 1, Day 29, Reach-Get Down 5 Lb Obj Above Head	99999	99999	99999	0
Par 1, Day 29, Climb Up Five Steps	99999	99999	99999	0
Par 1, Day 29, Walk Outdoors on Flat Ground	99999	99999	99999	0
Par 2, Week 12, Able to Do Chores	99999	99999	99999	0
Par 2, Week 12, Get In and Out of a car	99999	99999	99999	0
Par 2, Week 12, Run Errands and Shop	99999	99999	99999	0
Par 2, Week 12, Get In and Out of Bed	99999	99999	99999	0

Par 2, Week 12, Stand Up From a Straight Chair	99999	99999	99999	0
Par 2, Week 12, Dress yourself	99999	99999	99999	0
Par 2, Week 12, Shampoo your hair	99999	99999	99999	0
Par 2, Week 12, Cut your meat	99999	99999	99999	0
Par 2, Week 12, Lift a Full Cup or Glass to Mouth	99999	99999	99999	0
Par 2, Week 12, Open a New Milk Carton	99999	99999	99999	0
Par 2, Week 12, Open r car doors	99999	99999	99999	0
Par 2, Week 12, Open Jars Previously Opened	99999	99999	99999	0
Par 2, Week 12, Turn Faucets On And Off	99999	99999	99999	0
Par 2, Week 12, Get On and Off The Toilet	99999	99999	99999	0
Par 2, Week 12, Take a Tub Bath	99999	99999	99999	0
Par 2, Week 12, Wash and Dry Your Body	99999	99999	99999	0
Par 2, Week 12, Bend Down Pick Up Clothing- Floor	99999	99999	99999	1
Par 2, Week 12, Reach-Get Down 5 Lb Obj Above Head	99999	99999	99999	1
Par 2, Week 12, Climb Up Five Steps	99999	99999	99999	0
Par 2, Week 12, Walk Outdoors on Flat Ground	99999	99999	99999	0
Par 2, Day 113, Able to Do Chores	99999	99999	99999	0
Par 2, Day 113, Get In and Out of a car	99999	99999	99999	1
Par 2, Day 113, Run Errands and Shop	99999	99999	99999	0
Par 2, Day 113, Get In and Out of Bed	99999	99999	99999	0
Par 2, Day 113, Stand Up From a Straight Chair	99999	99999	99999	1
Par 2, Day 113, Dress yourself	99999	99999	99999	0
Par 2, Day 113, Shampoo your hair	99999	99999	99999	0
Par 2, Day 113, Cut your meat	99999	99999	99999	0
Par 2, Day 113, Lift a Full Cup or Glass to Mouth	99999	99999	99999	0
Par 2, Day 113, Open a New Milk Carton	99999	99999	99999	0
Par 2, Day 113, Open car doors	99999	99999	99999	0
Par 2, Day 113, Open Jars Previously Opened	99999	99999	99999	0
Par 2, Day 113, Turn Faucets On And Off	99999	99999	99999	0
Par 2, Day 113, Get On and Off The Toilet	99999	99999	99999	0
Par 2, Day 113, Take a Tub Bath	99999	99999	99999	0
Par 2, Day 113, Wash and Dry Your Body	99999	99999	99999	0
Par 2, Day 113, Bend Down Pick Up Clothing- Floor	99999	99999	99999	0
Par 2, Day 113, Reach-Get Down 5 Lb Obj Above Head	99999	99999	99999	1
Par 2, Day 113, Climb Up Five Steps	99999	99999	99999	0
Par 2, Day 113, Walk Outdoors on Flat Ground	99999	99999	99999	0
Par 3, Day 65, Able to Do Chores	99999	99999	99999	0
Par 3, Day 65, Get In and Out of a car	99999	99999	99999	0
Par 3, Day 65, Run Errands and Shop	99999	99999	99999	0

Par 3, Day 65, Get In and Out of Bed	99999	99999	99999	1
Par 3, Day 65, Stand Up From a Straight Chair	99999	99999	99999	1
Par 3, Day 65, Dress yourself	99999	99999	99999	0
Par 3, Day 65, Shampoo your hair	99999	99999	99999	0
Par 3, Day 65, Cut your meat	99999	99999	99999	0
Par 3, Day 65, Lift a Full Cup or Glass to Mouth	99999	99999	99999	0
Par 3, Day 65, Open a New Milk Carton	99999	99999	99999	0
Par 3, Day 65, Open car doors	99999	99999	99999	0
Par 3, Day 65, Open Jars Previously Opened	99999	99999	99999	0
Par 3, Day 65, Turn Faucets On And Off	99999	99999	99999	0
Par 3, Day 65, Get On and Off The Toilet	99999	99999	99999	0
Par 3, Day 65, Take a Tub Bath	99999	99999	99999	0
Par 3, Day 65, Wash and Dry Your Body	99999	99999	99999	0
Par 3, Day 65, Bend Down Pick Up Clothing- Floor	99999	99999	99999	0
Par 3, Day 65, Reach-Get Down 5 Lb Obj Above Head	99999	99999	99999	1
Par 3, Day 65, Climb Up Five Steps	99999	99999	99999	0
Par 3, Day 65, Walk Outdoors on Flat Ground	99999	99999	99999	0
Par 4, Week 12, Able to Do Chores	0	99999	99999	99999
Par 4, Week 12, Get In and Out of a car	0	99999	99999	99999
Par 4, Week 12, Run Errands and Shop	0	99999	99999	99999
Par 4, Week 12, Get In and Out of Bed	0	99999	99999	99999
Par 4, Week 12, Stand Up From a Straight Chair	0	99999	99999	99999
Par 4, Week 12, Dress yourself	0	99999	99999	99999
Par 4, Week 12, Shampoo your hair	0	99999	99999	99999
Par 4, Week 12, Cut your meat	0	99999	99999	99999
Par 4, Week 12, Lift a Full Cup or Glass to Mouth	0	99999	99999	99999
Par 4, Week 12, Open a New Milk Carton	0	99999	99999	99999
Par 4, Week 12, Open car doors	0	99999	99999	99999
Par 4, Week 12, Open Jars Previously Opened	0	99999	99999	99999
Par 4, Week 12, Turn Faucets On And Off	0	99999	99999	99999
Par 4, Week 12, Get On and Off The Toilet	0	99999	99999	99999
Par 4, Week 12, Take a Tub Bath	0	99999	99999	99999
Par 4, Week 12, Wash and Dry Your Body	0	99999	99999	99999
Par 4, Week 12, Bend Down Pick Up Clothing- Floor	0	99999	99999	99999
Par 4, Week 12, Reach-Get Down 5 Lb Obj Above Head	0	99999	99999	99999
Par 4, Week 12, Climb Up Five Steps	0	99999	99999	99999
Par 4, Week 12, Walk Outdoors on Flat Ground	0	99999	99999	99999
Par 4, Day 373, Able to Do Chores	0	99999	99999	99999
Par 4, Day 373, Get In and Out of a car	0	99999	99999	99999
Par 4, Day 373, Run Errands and Shop	0	99999	99999	99999
Par 4, Day 373, Get In and Out of Bed	0	99999	99999	99999

Par 4, Day 373, Stand Up From a Straight Chair	0	99999	99999	99999
Par 4, Day 373, Dress yourself	0	99999	99999	99999
Par 4, Day 373, Shampoo your hair	0	99999	99999	99999
Par 4, Day 373, Cut your meat	0	99999	99999	99999
Par 4, Day 373, Lift a Full Cup or Glass to Mouth	0	99999	99999	99999
Par 4, Day 373, Open a New Milk Carton	0	99999	99999	99999
Par 4, Day 373, Open car doors	0	99999	99999	99999
Par 4, Day 373, Open Jars Previously Opened	0	99999	99999	99999
Par 4, Day 373, Turn Faucets On And Off	0	99999	99999	99999
Par 4, Day 373, Get On and Off The Toilet	0	99999	99999	99999
Par 4, Day 373, Take a Tub Bath	0	99999	99999	99999
Par 4, Day 373, Wash and Dry Your Body	0	99999	99999	99999
Par 4, Day 373, Bend Down Pick Up Clothing- Floor	0	99999	99999	99999
Par 4, Day 373, Reach-Get Down 5 Lb Obj Above Head	0	99999	99999	99999
Par 4, Day 373, Climb Up Five Steps	0	99999	99999	99999
Par 4, Day 373, Walk Outdoors on Flat Ground	0	99999	99999	99999
Par 5, Day 64, Able to Do Chores	0	99999	99999	99999
Par 5, Day 64, Get In and Out of a car	0	99999	99999	99999
Par 5, Day 64, Run Errands and Shop	0	99999	99999	99999
Par 5, Day 64, Get In and Out of Bed	0	99999	99999	99999
Par 5, Day 64, Stand Up From a Straight Chair	0	99999	99999	99999
Par 5, Day 64, Dress yourself	1	99999	99999	99999
Par 5, Day 64, Shampoo your hair	0	99999	99999	99999
Par 5, Day 64, Cut your meat	0	99999	99999	99999
Par 5, Day 64, Lift a Full Cup or Glass to Mouth	0	99999	99999	99999
Par 5, Day 64, Open a New Milk Carton	0	99999	99999	99999
Par 5, Day 64, Open car doors	0	99999	99999	99999
Par 5, Day 64, Open Jars Previously Opened	0	99999	99999	99999
Par 5, Day 64, Turn Faucets On And Off	0	99999	99999	99999
Par 5, Day 64, Get On and Off The Toilet	0	99999	99999	99999
Par 5, Day 64, Take a Tub Bath	0	99999	99999	99999
Par 5, Day 64, Wash and Dry Your Body	0	99999	99999	99999
Par 5, Day 64, Bend Down Pick Up Clothing- Floor	1	99999	99999	99999
Par 5, Day 64, Reach-Get Down 5 Lb Obj Above Head	1	99999	99999	99999
Par 5, Day 64, Climb Up Five Steps	1	99999	99999	99999
Par 5, Day 64, Walk Outdoors on Flat Ground	1	99999	99999	99999
Par 6, Day 85 Able to Do Chores	99999	1	99999	99999
Par 6, Day 85, Get In and Out of a car	99999	0	99999	99999
Par 6, Day 85, Run Errands and Shop	99999	0	99999	99999
Par 6, Day 85, Get In and Out of Bed	99999	0	99999	99999
Par 6, Day 85, Stand Up From a Straight Chair	99999	0	99999	99999

Par 6, Day 85, Dress yourself	99999	0	99999	99999
Par 6, Day 85, Shampoo your hair	99999	0	99999	99999
Par 6, Day 85, Cut your meat	99999	0	99999	99999
Par 6, Day 85, Lift a Full Cup or Glass to Mouth	99999	0	99999	99999
Par 6, Day 85, Open a New Milk Carton	99999	0	99999	99999
Par 6, Day 85, Open car doors	99999	0	99999	99999
Par 6, Day 85, Open Jars Previously Opened	99999	1	99999	99999
Par 6, Day 85, Turn Faucets On And Off	99999	0	99999	99999
Par 6, Day 85, Get On and Off The Toilet	99999	0	99999	99999
Par 6, Day 85, Take a Tub Bath	99999	1	99999	99999
Par 6, Day 85, Wash and Dry Your Body	99999	0	99999	99999
Par 6, Day 85, Bend Down Pick Up Clothing- Floor	99999	0	99999	99999
Par 6, Day 85, Reach-Get Down 5 Lb Obj Above Head	99999	0	99999	99999
Par 6, Day 85, Climb Up Five Steps	99999	0	99999	99999
Par 6, Day 85, Walk Outdoors on Flat Ground	99999	0	99999	99999
Par 7, Day 169, Able to Do Chores	99999	99999	99999	99999
Par 7, Day 169, Get In and Out of a car	99999	99999	99999	99999
Par 7, Day 169, Run Errands and Shop	99999	99999	99999	99999
Par 7, Day 169, Get In and Out of Bed	99999	99999	99999	99999
Par 7, Day 169, Stand Up From a Straight Chair	99999	99999	99999	99999
Par 7, Day 169, Dress yourself	99999	99999	99999	99999
Par 7, Day 169, Shampoo your hair	99999	99999	99999	99999
Par 7, Day 169, Cut your meat	99999	99999	99999	99999
Par 7, Day 169, Lift a Full Cup or Glass to Mouth	99999	99999	99999	99999
Par 7, Day 169, Open a New Milk Carton	99999	99999	99999	99999
Par 7, Day 169, Open car doors	99999	99999	99999	99999
Par 7, Day 169, Open Jars Previously Opened	99999	99999	99999	99999
Par 7, Day 169, Turn Faucets On And Off	99999	99999	99999	99999
Par 7, Day 169, Get On and Off The Toilet	99999	99999	99999	99999
Par 7, Day 169, Take a Tub Bath	99999	99999	99999	99999
Par 7, Day 169, Wash and Dry Your Body	99999	99999	99999	99999
Par 7, Day 169, Bend Down Pick Up Clothing- Floor	99999	99999	99999	99999
Par 7, Day 169, Reach-Get Down 5 Lb Obj Above Head	99999	99999	99999	99999
Par 7, Day 169, Climb Up Five Steps	99999	99999	99999	99999
Par 7, Day 169, Walk Outdoors on Flat Ground	99999	99999	99999	99999
Par 8, Week 12, Able to Do Chores	99999	99999	0	99999
Par 8, Week 12, Get In and Out of a car	99999	99999	0	99999
Par 8, Week 12, Run Errands and Shop	99999	99999	0	99999
Par 8, Week 12, Get In and Out of Bed	99999	99999	0	99999
Par 8, Week 12, Stand Up From a Straight Chair	99999	99999	0	99999
Par 8, Week 12, Dress yourself	99999	99999	0	99999
Par 8, Week 12, Shampoo your hair	99999	99999	0	99999

Par 8, Week 12, Cut your meat	99999	99999	0	99999
Par 8, Week 12, Lift a Full Cup or Glass to Mouth	99999	99999	0	99999
Par 8, Week 12, Open a New Milk Carton	99999	99999	0	99999
Par 8, Week 12, Open car doors	99999	99999	0	99999
Par 8, Week 12, Open Jars Previously Opened	99999	99999	0	99999
Par 8, Week 12, Turn Faucets On And Off	99999	99999	0	99999
Par 8, Week 12, Get On and Off The Toilet	99999	99999	0	99999
Par 8, Week 12, Take a Tub Bath	99999	99999	0	99999
Par 8, Week 12, Wash and Dry Your Body	99999	99999	0	99999
Par 8, Week 12, Bend Down Pick Up Clothing- Floor	99999	99999	0	99999
Par 8, Week 12 Reach-Get Down 5 Lb Obj Above Head	99999	99999	0	99999
Par 8, Week 12, Climb Up Five Steps	99999	99999	0	99999
Par 8, Week 12, Walk Outdoors on Flat Ground	99999	99999	0	99999
Par 8, Day 112, Able to Do Chores	99999	99999	0	99999
Par 8, Day 112, Get In and Out of a car	99999	99999	0	99999
Par 8, Day 112, Run Errands and Shop	99999	99999	0	99999
Par 8, Day 112, Get In and Out of Bed	99999	99999	0	99999
Par 8, Day 112, Stand Up From a Straight Chair	99999	99999	0	99999
Par 8, Day 112, Dress yourself	99999	99999	0	99999
Par 8, Day 112, Shampoo your hair	99999	99999	0	99999
Par 8, Day 112, Cut your meat	99999	99999	0	99999
Par 8, Day 112, Lift a Full Cup or Glass to Mout	99999	99999	0	99999
Par 8, Day 112, Open a New Milk Carton	99999	99999	0	99999
Par 8, Day 112, Open car doors	99999	99999	0	99999
Par 8, Day 112, Open Jars Previously Opened	99999	99999	0	99999
Par 8, Day 112, Turn Faucets On And Off	99999	99999	0	99999
Par 8, Day 112, Get On and Off The Toilet	99999	99999	0	99999
Par 8, Day 112, Take a Tub Bath	99999	99999	0	99999
Par 8, Day 112, Wash and Dry Your Body	99999	99999	0	99999
Par 8, Day 112, Bend Down Pick Up Clothing- Floor	99999	99999	0	99999
Par 8, Day 112, Reach-Get Down 5 Lb Obj Above Head	99999	99999	0	99999
Par 8, Day 112, Climb Up Five Steps	99999	99999	0	99999
Par 8, Day 112, Walk Outdoors on Flat Ground	99999	99999	0	99999

End point values	PartB:Placebo SC q2w + 6 month prednisone			
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Subject group type	Subject analysis set			
Number of subjects analysed	1			
Units: Scores on scale				
number (not applicable)				
Par 1, Day 29, Able to Do Chores	99999			
Par 1, Day 29, Get In and Out of a car	99999			
Par 1, Day 29, Run Errands and Shop	99999			
Par 1, Day 29, Get In and Out of Bed	99999			
Par 1, Day 29, Stand Up From a Straight Chair	99999			
Par 1, Day 29, Dress yourself	99999			
Par 1, Day 29, Shampoo your hair	99999			
Par 1, Day 29, Cut your meat	99999			
Par 1, Day 29, Lift a Full Cup or Glass to Mouth	99999			
Par 1, Day 29, Open a New Milk Carton	99999			
Par 1, Day 29, Open car doors	99999			
Par 1, Day 29, Open Jars Previously Opened	99999			
Par 1, Day 29, Turn Faucets On And Off	99999			
Par 1, Day 29, Get On and Off The Toilet	99999			
Par 1, Day 29, Take a Tub Bath	99999			
Par 1, Day 29, Wash and Dry Your Body	99999			
Par 1, Day 29, Bend Down Pick Up Clothing- Floor	99999			
Par 1, Day 29, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 1, Day 29, Climb Up Five Steps	99999			
Par 1, Day 29, Walk Outdoors on Flat Ground	99999			
Par 2, Week 12, Able to Do Chores	99999			
Par 2, Week 12, Get In and Out of a car	99999			
Par 2, Week 12, Run Errands and Shop	99999			
Par 2, Week 12, Get In and Out of Bed	99999			
Par 2, Week 12, Stand Up From a Straight Chair	99999			
Par 2, Week 12, Dress yourself	99999			
Par 2, Week 12, Shampoo your hair	99999			
Par 2, Week 12, Cut your meat	99999			
Par 2, Week 12, Lift a Full Cup or Glass to Mouth	99999			
Par 2, Week 12, Open a New Milk Carton	99999			
Par 2, Week 12, Open r car doors	99999			
Par 2, Week 12, Open Jars Previously Opened	99999			
Par 2, Week 12, Turn Faucets On And Off	99999			
Par 2, Week 12, Get On and Off The Toilet	99999			
Par 2, Week 12, Take a Tub Bath	99999			
Par 2, Week 12, Wash and Dry Your Body	99999			
Par 2, Week 12, Bend Down Pick Up Clothing- Floor	99999			
Par 2, Week 12, Reach-Get Down 5 Lb Obj Above Head	99999			

Par 2, Week 12, Climb Up Five Steps	99999			
Par 2, Week 12, Walk Outdoors on Flat Ground	99999			
Par 2, Day 113, Able to Do Chores	99999			
Par 2, Day 113, Get In and Out of a car	99999			
Par 2, Day 113, Run Errands and Shop	99999			
Par 2, Day 113, Get In and Out of Bed	99999			
Par 2, Day 113, Stand Up From a Straight Chair	99999			
Par 2, Day 113, Dress yourself	99999			
Par 2, Day 113, Shampoo your hair	99999			
Par 2, Day 113, Cut your meat	99999			
Par 2, Day 113, Lift a Full Cup or Glass to Mouth	99999			
Par 2, Day 113, Open a New Milk Carton	99999			
Par 2, Day 113, Open car doors	99999			
Par 2, Day 113, Open Jars Previously Opened	99999			
Par 2, Day 113, Turn Faucets On And Off	99999			
Par 2, Day 113, Get On and Off The Toilet	99999			
Par 2, Day 113, Take a Tub Bath	99999			
Par 2, Day 113, Wash and Dry Your Body	99999			
Par 2, Day 113, Bend Down Pick Up Clothing- Floor	99999			
Par 2, Day 113, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 2, Day 113, Climb Up Five Steps	99999			
Par 2, Day 113, Walk Outdoors on Flat Ground	99999			
Par 3, Day 65, Able to Do Chores	99999			
Par 3, Day 65, Get In and Out of a car	99999			
Par 3, Day 65, Run Errands and Shop	99999			
Par 3, Day 65, Get In and Out of Bed	99999			
Par 3, Day 65, Stand Up From a Straight Chair	99999			
Par 3, Day 65, Dress yourself	99999			
Par 3, Day 65, Shampoo your hair	99999			
Par 3, Day 65, Cut your meat	99999			
Par 3, Day 65, Lift a Full Cup or Glass to Mouth	99999			
Par 3, Day 65, Open a New Milk Carton	99999			
Par 3, Day 65, Open car doors	99999			
Par 3, Day 65, Open Jars Previously Opened	99999			
Par 3, Day 65, Turn Faucets On And Off	99999			
Par 3, Day 65, Get On and Off The Toilet	99999			
Par 3, Day 65, Take a Tub Bath	99999			
Par 3, Day 65, Wash and Dry Your Body	99999			
Par 3, Day 65, Bend Down Pick Up Clothing- Floor	99999			
Par 3, Day 65, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 3, Day 65, Climb Up Five Steps	99999			

Par 3, Day 65, Walk Outdoors on Flat Ground	99999			
Par 4, Week 12, Able to Do Chores	99999			
Par 4, Week 12, Get In and Out of a car	99999			
Par 4, Week 12, Run Errands and Shop	99999			
Par 4, Week 12, Get In and Out of Bed	99999			
Par 4, Week 12, Stand Up From a Straight Chair	99999			
Par 4, Week 12, Dress yourself	99999			
Par 4, Week 12, Shampoo your hair	99999			
Par 4, Week 12, Cut your meat	99999			
Par 4, Week 12, Lift a Full Cup or Glass to Mouth	99999			
Par 4, Week 12, Open a New Milk Carton	99999			
Par 4, Week 12, Open car doors	99999			
Par 4, Week 12, Open Jars Previously Opened	99999			
Par 4, Week 12, Turn Faucets On And Off	99999			
Par 4, Week 12, Get On and Off The Toilet	99999			
Par 4, Week 12, Take a Tub Bath	99999			
Par 4, Week 12, Wash and Dry Your Body	99999			
Par 4, Week 12, Bend Down Pick Up Clothing- Floor	99999			
Par 4, Week 12, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 4, Week 12, Climb Up Five Steps	99999			
Par 4, Week 12, Walk Outdoors on Flat Ground	99999			
Par 4, Day 373, Able to Do Chores	99999			
Par 4, Day 373, Get In and Out of a car	99999			
Par 4, Day 373, Run Errands and Shop	99999			
Par 4, Day 373, Get In and Out of Bed	99999			
Par 4, Day 373, Stand Up From a Straight Chair	99999			
Par 4, Day 373, Dress yourself	99999			
Par 4, Day 373, Shampoo your hair	99999			
Par 4, Day 373, Cut your meat	99999			
Par 4, Day 373, Lift a Full Cup or Glass to Mouth	99999			
Par 4, Day 373, Open a New Milk Carton	99999			
Par 4, Day 373, Open car doors	99999			
Par 4, Day 373, Open Jars Previously Opened	99999			
Par 4, Day 373, Turn Faucets On And Off	99999			
Par 4, Day 373, Get On and Off The Toilet	99999			
Par 4, Day 373, Take a Tub Bath	99999			
Par 4, Day 373, Wash and Dry Your Body	99999			
Par 4, Day 373, Bend Down Pick Up Clothing- Floor	99999			
Par 4, Day 373, Reach-Get Down 5 Lb Obj Above Head	99999			

Par 4, Day 373, Climb Up Five Steps	99999			
Par 4, Day 373, Walk Outdoors on Flat Ground	99999			
Par 5, Day 64, Able to Do Chores	99999			
Par 5, Day 64, Get In and Out of a car	99999			
Par 5, Day 64, Run Errands and Shop	99999			
Par 5, Day 64, Get In and Out of Bed	99999			
Par 5, Day 64, Stand Up From a Straight Chair	99999			
Par 5, Day 64, Dress yourself	99999			
Par 5, Day 64, Shampoo your hair	99999			
Par 5, Day 64, Cut your meat	99999			
Par 5, Day 64, Lift a Full Cup or Glass to Mouth	99999			
Par 5, Day 64, Open a New Milk Carton	99999			
Par 5, Day 64, Open car doors	99999			
Par 5, Day 64, Open Jars Previously Opened	99999			
Par 5, Day 64, Turn Faucets On And Off	99999			
Par 5, Day 64, Get On and Off The Toilet	99999			
Par 5, Day 64, Take a Tub Bath	99999			
Par 5, Day 64, Wash and Dry Your Body	99999			
Par 5, Day 64, Bend Down Pick Up Clothing- Floor	99999			
Par 5, Day 64, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 5, Day 64, Climb Up Five Steps	99999			
Par 5, Day 64, Walk Outdoors on Flat Ground	99999			
Par 6, Day 85 Able to Do Chores	99999			
Par 6, Day 85, Get In and Out of a car	99999			
Par 6, Day 85, Run Errands and Shop	99999			
Par 6, Day 85, Get In and Out of Bed	99999			
Par 6, Day 85, Stand Up From a Straight Chair	99999			
Par 6, Day 85, Dress yourself	99999			
Par 6, Day 85, Shampoo your hair	99999			
Par 6, Day 85, Cut your meat	99999			
Par 6, Day 85, Lift a Full Cup or Glass to Mouth	99999			
Par 6, Day 85, Open a New Milk Carton	99999			
Par 6, Day 85, Open car doors	99999			
Par 6, Day 85, Open Jars Previously Opened	99999			
Par 6, Day 85, Turn Faucets On And Off	99999			
Par 6, Day 85, Get On and Off The Toilet	99999			
Par 6, Day 85, Take a Tub Bath	99999			
Par 6, Day 85, Wash and Dry Your Body	99999			
Par 6, Day 85, Bend Down Pick Up Clothing- Floor	99999			
Par 6, Day 85, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 6, Day 85, Climb Up Five Steps	99999			
Par 6, Day 85, Walk Outdoors on Flat Ground	99999			
Par 7, Day 169, Able to Do Chores	0			

Par 7, Day 169, Get In and Out of a car	0			
Par 7, Day 169, Run Errands and Shop	0			
Par 7, Day 169, Get In and Out of Bed	0			
Par 7, Day 169, Stand Up From a Straight Chair	0			
Par 7, Day 169, Dress yourself	0			
Par 7, Day 169, Shampoo your hair	0			
Par 7, Day 169, Cut your meat	0			
Par 7, Day 169, Lift a Full Cup or Glass to Mouth	0			
Par 7, Day 169, Open a New Milk Carton	0			
Par 7, Day 169, Open car doors	0			
Par 7, Day 169, Open Jars Previously Opened	0			
Par 7, Day 169, Turn Faucets On And Off	0			
Par 7, Day 169, Get On and Off The Toilet	0			
Par 7, Day 169, Take a Tub Bath	0			
Par 7, Day 169, Wash and Dry Your Body	0			
Par 7, Day 169, Bend Down Pick Up Clothing- Floor	0			
Par 7, Day 169, Reach-Get Down 5 Lb Obj Above Head	0			
Par 7, Day 169, Climb Up Five Steps	0			
Par 7, Day 169, Walk Outdoors on Flat Ground	0			
Par 8, Week 12, Able to Do Chores	99999			
Par 8, Week 12, Get In and Out of a car	99999			
Par 8, Week 12, Run Errands and Shop	99999			
Par 8, Week 12, Get In and Out of Bed	99999			
Par 8, Week 12, Stand Up From a Straight Chair	99999			
Par 8, Week 12, Dress yourself	99999			
Par 8, Week 12, Shampoo your hair	99999			
Par 8, Week 12, Cut your meat	99999			
Par 8, Week 12, Lift a Full Cup or Glass to Mouth	99999			
Par 8, Week 12, Open a New Milk Carton	99999			
Par 8, Week 12, Open car doors	99999			
Par 8, Week 12, Open Jars Previously Opened	99999			
Par 8, Week 12, Turn Faucets On And Off	99999			
Par 8, Week 12, Get On and Off The Toilet	99999			
Par 8, Week 12, Take a Tub Bath	99999			
Par 8, Week 12, Wash and Dry Your Body	99999			
Par 8, Week 12, Bend Down Pick Up Clothing- Floor	99999			
Par 8, Week 12, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 8, Week 12, Climb Up Five Steps	99999			
Par 8, Week 12, Walk Outdoors on Flat Ground	99999			

Par 8, Day 112, Able to Do Chores	99999			
Par 8, Day 112, Get In and Out of a car	99999			
Par 8, Day 112, Run Errands and Shop	99999			
Par 8, Day 112, Get In and Out of Bed	99999			
Par 8, Day 112, Stand Up From a Straight Chair	99999			
Par 8, Day 112, Dress yourself	99999			
Par 8, Day 112, Shampoo your hair	99999			
Par 8, Day 112, Cut your meat	99999			
Par 8, Day 112, Lift a Full Cup or Glass to Mout	99999			
Par 8, Day 112, Open a New Milk Carton	99999			
Par 8, Day 112, Open car doors	99999			
Par 8, Day 112, Open Jars Previously Opened	99999			
Par 8, Day 112, Turn Faucets On And Off	99999			
Par 8, Day 112, Get On and Off The Toilet	99999			
Par 8, Day 112, Take a Tub Bath	99999			
Par 8, Day 112, Wash and Dry Your Body	99999			
Par 8, Day 112, Bend Down Pick Up Clothing- Floor	99999			
Par 8, Day 112, Reach-Get Down 5 Lb Obj Above Head	99999			
Par 8, Day 112, Climb Up Five Steps	99999			
Par 8, Day 112, Walk Outdoors on Flat Ground	99999			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in PtGA score for participants who received at least one dose of 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in PtGA score for participants who received at least one dose of 100 mg OL Sirukumab in Part B
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End point description:

The Patient's Global Assessments of Disease Activity was recorded on a Visual analog scale (VAS). of 10 centimeter (cm) ranging from 0 ("very well) to 10 ("very poor"). Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Day 0), Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38, 40; Days 85, 87, 91, , 113, 162, 339, and 344

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Scores on scale				
number (not applicable)				
Par 1, Week 2	4.3	99999	99999	99999
Par 1, Week 4	2.3	99999	99999	99999
Par 1, Week 8	-0.2	99999	99999	99999
Par 1, Week 12	4.0	99999	99999	99999
Par 1, Week 16	4.7	99999	99999	99999
Par 1, Week 24	2.2	99999	99999	99999
Par 1, Week 36	0.4	99999	99999	99999
Par 1, Day 339	-0.7	99999	99999	99999
Par 2, Week 4	-1.0	99999	99999	99999
Par 2, Week 8	-0.3	99999	99999	99999
Par 2, Week 12	-0.6	99999	99999	99999
Par 2, Week 16	-0.7	99999	99999	99999
Par 2, Week 24	0.5	99999	99999	99999
Par 2, Week 36	-0.6	99999	99999	99999
Par 2, Week 38	0.9	99999	99999	99999
Par 2, Week 40	-0.3	99999	99999	99999
Par 2, Day 344	-0.7	99999	99999	99999
Par 3,Par 3,, Day 113	99999	99999	2.1	99999
Par 4, Week 4	99999	-1.0	99999	99999
Par 4, Week 8	99999	4.9	99999	99999
Par 4, Week 12	99999	0.4	99999	99999
Par 5, Week 4	99999	99999	99999	2.0
Par 5, Week 8	99999	99999	99999	99999
Par 5, Week 12	99999	99999	99999	0.2
Par 5, Week 14	99999	99999	99999	1.0
Par 5, Week 16	99999	99999	99999	1.0
Par 5, Day 162	99999	99999	99999	0.8
Par 6, Week 4	99999	99999	99999	-3.1
Par 6, Week 8	99999	99999	99999	-3.2
Par 6, Day 91	99999	99999	99999	-3.5
Par 7, Week 2	99999	99999	99999	99999
Par 7, Week 4	99999	99999	99999	99999
Par 7, Week 8	99999	99999	99999	99999
Par 7, Day 85	99999	99999	99999	99999
Par 8, Week 2	99999	99999	99999	99999
Par 8, Week 4	99999	99999	99999	99999
Par 8, Day 87	99999	99999	99999	99999
Par 6, Week 2	99999	99999	99999	-0.1

End point values	PartB:Placebo SC q2w + 12 month prednisone			
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Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Scores on scale				
number (not applicable)				
Par 1, Week 2	99999			
Par 1, Week 4	99999			
Par 1, Week 8	99999			
Par 1, Week 12	99999			
Par 1, Week 16	99999			
Par 1, Week 24	99999			
Par 1, Week 36	99999			
Par 1, Day 339	99999			
Par 2, Week 4	99999			
Par 2, Week 8	99999			
Par 2, Week 12	99999			
Par 2, Week 16	99999			
Par 2, Week 24	99999			
Par 2, Week 36	99999			
Par 2, Week 38	99999			
Par 2, Week 40	99999			
Par 2, Day 344	99999			
Par 3,Par 3,, Day 113	99999			
Par 4, Week 4	99999			
Par 4, Week 8	99999			
Par 4, Week 12	99999			
Par 5, Week 4	99999			
Par 5, Week 8	0.4			
Par 5, Week 12	99999			
Par 5, Week 14	99999			
Par 5, Week 16	99999			
Par 5, Day 162	99999			
Par 6, Week 4	99999			
Par 6, Week 8	99999			
Par 6, Day 91	99999			
Par 7, Week 2	-0.7			
Par 7, Week 4	0.7			
Par 7, Week 8	0.8			
Par 7, Day 85	-0.4			
Par 8, Week 2	-0.1			
Par 8, Week 4	-3.7			
Par 8, Day 87	-3.1			
Par 6, Week 2	99999			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in PtGA score for participants who never received 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in PtGA score for participants who never received 100 mg OL Sirukumab in Part B
End point description:	
The Patient's Global Assessments of Disease Activity was recorded on a Visual analog scale (VAS). of 10 centimeter (cm) ranging from 0 ("very well") to 10 ("very poor"). Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Participants with post baseline data were reported.	
End point type	Secondary
End point timeframe:	
Baseline (Day 0), Weeks 2, 4, 8, 12, 16, 36; Days 23, 29, 30, 57, 59, 64, 65, 85,112, 113, 115, 163, 169 and 373	

End point values	PartB:Placebo SC q2w + 6 month prednisone	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	2	6	4
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30	99999	99999	0.2	99999
Par 2, Day 29	99999	99999	-0.1	99999
Par 3, Day 23	99999	99999	0.0	99999
Par 4, Week 4	99999	99999	-0.2	99999
Par 4, Week 8	99999	99999	0.1	99999
Par 4, Week 12	99999	99999	0.0	99999
Par 4, Day 113	99999	99999	0.0	99999
Par 5, Week 4	99999	99999	0.1	99999
Par 5, Week 8	99999	99999	0.4	99999
Par 5, Day 85	99999	99999	2.3	99999
Par 6, Week 4	99999	99999	-1.0	99999
Par 6, Day 65	99999	99999	0.5	99999
Par 7, Week 4	99999	99999	99999	1.0
Par 7, Week 8	99999	99999	99999	0.0
Par 7, Week 12	99999	99999	99999	0.0
Par 7, Week 16	99999	99999	99999	0.2
Par 7, Week 36	99999	99999	99999	0.2
Par 7, Day 373	99999	99999	99999	0.9
Par 8, Week 4	99999	99999	99999	-0.2
Par 8, Day 64	99999	99999	99999	-0.4
Par 9, Day 29	99999	99999	99999	0.1
Par 10, Week 4	99999	99999	99999	0.0
Par 10, Day 57	99999	99999	99999	-0.3
Par 11, Week 4	99999	99999	99999	99999
Par 11, Week 8	99999	99999	99999	99999
Par 11, Week 12	99999	99999	99999	99999
Par 11, Week 16	99999	99999	99999	99999
Par 11, Day 163	99999	99999	99999	99999
Par 12, Day 4	99999	99999	99999	99999
Par 12, Week 8	99999	99999	99999	99999
Par 12, Day 85	99999	99999	99999	99999

Par 12, Week 4	99999	99999	99999	99999
Par 12, Day 59	99999	99999	99999	99999
Par 13, Week 4	-0.4	99999	99999	99999
Par 13, Day 57	-0.9	99999	99999	99999
Par 14, Day 169	-1.1	99999	99999	99999
Par 15, Week 4	99999	-0.3	99999	99999
Par 15, Week 12	99999	-0.3	99999	99999
Par 15, Day 112	99999	-0.1	99999	99999
Par 16, Week 8	99999	0.2	99999	99999
Par 16, Day 85	99999	-0.1	99999	99999

End point values	PartB:SIR 50 mg SC q4w+6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30	99999			
Par 2, Day 29	99999			
Par 3, Day 23	99999			
Par 4, Week 4	99999			
Par 4, Week 8	99999			
Par 4, Week 12	99999			
Par 4, Day 113	99999			
Par 5, Week 4	99999			
Par 5, Week 8	99999			
Par 5, Day 85	99999			
Par 6, Week 4	99999			
Par 6, Day 65	99999			
Par 7, Week 4	99999			
Par 7, Week 8	99999			
Par 7, Week 12	99999			
Par 7, Week 16	99999			
Par 7, Week 36	99999			
Par 7, Day 373	99999			
Par 8, Week 4	99999			
Par 8, Day 64	99999			
Par 9, Day 29	99999			
Par 10, Week 4	99999			
Par 10, Day 57	99999			
Par 11, Week 4	-0.1			
Par 11, Week 8	0.2			
Par 11, Week 12	0.2			
Par 11, Week 16	1.2			
Par 11, Day 163	0.3			
Par 12, Day 4	-0.8			
Par 12, Week 8	-0.7			
Par 12, Day 85	0.9			

Par 12, Week 4	-0.7			
Par 12, Day 59	1.0			
Par 13, Week 4	99999			
Par 13, Day 57	99999			
Par 14, Day 169	99999			
Par 15, Week 4	99999			
Par 15, Week 12	99999			
Par 15, Day 112	99999			
Par 16, Week 8	99999			
Par 16, Day 85	99999			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in PhGA score for participants who received at least one dose of 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in PhGA score for participants who received at least one dose of 100 mg OL Sirukumab in Part B
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End point description:

In PhGA was based on "What is physician's assessment of the participant's current disease activity". PhGA used a 10 cm VAS ranging from 0 ("none") to 10 ("extremely active"). Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Day 0) and Day 85, Day 113, Day 162, Day 203, Day 339, Day 344, Week 2, Week 4, Week 8, Week 12, Week 14, Week 16, Week 24, Week 36, Week 38, Week 40

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Scores on scale				
number (not applicable)				
Par 1, Week 2	0.0	99999	99999	99999
Par 1, Week 4	-0.5	99999	99999	99999
Par 1, Week 8	-1.2	99999	99999	99999
Par 1, Week 12	-0.6	99999	99999	99999
Par 1, Week 16	-0.9	99999	99999	99999
Par 1, Week 24	-0.6	99999	99999	99999
Par 1, Week 36	-1.1	99999	99999	99999
Par 1, Day 339	-1.2	99999	99999	99999
Par 2, Week 4	0.0	99999	99999	99999
Par 2, Week 8	0.1	99999	99999	99999
Par 2, Week 12	0.4	99999	99999	99999

Par 2, Week 16	0.1	99999	99999	99999
Par 2, Week 24	0.0	99999	99999	99999
Par 2, Week 36	0.1	99999	99999	99999
Par 2, Week 38	0.7	99999	99999	99999
Par 2, Week 40	0.4	99999	99999	99999
Par 2, Day 344	0.2	99999	99999	99999
Par 3, Day 113	99999	99999	-0.2	99999
Par 4, Week 4	99999	-0.2	99999	99999
Par 4, Week 12	99999	0.1	99999	99999
Par 5, Week 4	99999	99999	99999	1.8
Par 5, Week 8	99999	99999	99999	-1.1
Par 5, Week 12	99999	99999	99999	-0.7
Par 5, Week 14	99999	99999	99999	1.5
Par 5, Week 16	99999	99999	99999	-1.1
Par 5, Day 162	99999	99999	99999	-0.4
Par 6, Day 203	99999	99999	99999	7.6
Par 7, Week 2	99999	99999	99999	99999
Par 7, Week 4	99999	99999	99999	99999
Par 7, Week 8	99999	99999	99999	99999
Par 7, Day 85	99999	99999	99999	99999
Par 8, Week 2	99999	99999	99999	99999
Par 8, Week 4	99999	99999	99999	99999

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Scores on scale				
number (not applicable)				
Par 1, Week 2	99999			
Par 1, Week 4	99999			
Par 1, Week 8	99999			
Par 1, Week 12	99999			
Par 1, Week 16	99999			
Par 1, Week 24	99999			
Par 1, Week 36	99999			
Par 1, Day 339	99999			
Par 2, Week 4	99999			
Par 2, Week 8	99999			
Par 2, Week 12	99999			
Par 2, Week 16	99999			
Par 2, Week 24	99999			
Par 2, Week 36	99999			
Par 2, Week 38	99999			
Par 2, Week 40	99999			
Par 2, Day 344	99999			
Par 3, Day 113	99999			
Par 4, Week 4	99999			

Par 4, Week 12	99999			
Par 5, Week 4	99999			
Par 5, Week 8	99999			
Par 5, Week 12	99999			
Par 5, Week 14	99999			
Par 5, Week 16	99999			
Par 5, Day 162	99999			
Par 6, Day 203	99999			
Par 7, Week 2	0.0			
Par 7, Week 4	0.1			
Par 7, Week 8	0.0			
Par 7, Day 85	0.0			
Par 8, Week 2	-6.0			
Par 8, Week 4	-6.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in PhGA score for participants who never received 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in PhGA score for participants who never received 100 mg OL Sirukumab in Part B
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End point description:

In PhGA was based on "What is physician's assessment of the participant's current disease activity". PhGA used a 10 cm VAS ranging from 0 ("none") to 10 ("extremely active"). Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value. Participants with post baseline data were reported.

End point type	Secondary
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End point timeframe:

Baseline (Day 0), Weeks 4, 8, 12, 16, 36; Days 23, 29, 30, 57, 59, 64, 65, 85, 112, 113, 163, 169 and 373

End point values	PartB:Placebo SC q2w + 6 month prednisone	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	2	6	4
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30	99999	99999	0.0	99999
Par 2, Day 29	99999	99999	0.1	99999
Par 3, Day 23	99999	99999	0.0	99999
Par 3, Week 12	99999	99999	0.7	99999
Par 4, Day 113	99999	99999	0.0	99999
Par 5, Week 4	99999	99999	-0.3	99999
Par 5, Day 85	99999	99999	0.3	99999
Par 6, Week 4	99999	99999	-0.2	99999

Par 6, Day 65	99999	99999	-0.3	99999
Par 7, Week 4	99999	99999	99999	0.2
Par 7, Week 8	99999	99999	99999	0.0
Par 7, Week 12	99999	99999	99999	0.2
Par 7, Week 16	99999	99999	99999	0.4
Par 7, Week 36	99999	99999	99999	0.2
Par 7, Day 373	99999	99999	99999	0.0
Par 8, Week 4	99999	99999	99999	0.4
Par 8, Day 64	99999	99999	99999	0.1
Par 9, Day 29	99999	99999	99999	0.2
Par 10, Week 4	99999	99999	99999	0.0
Par 10, Day 57	99999	99999	99999	0.1
Par 11, Week 12	99999	99999	99999	99999
Par 11, Week 16	99999	99999	99999	99999
Par 11, Day 163	99999	99999	99999	99999
Par 12, Week 4	99999	99999	99999	99999
Par 12, Week 8	99999	99999	99999	99999
Par 12, Day 85	99999	99999	99999	99999
Par 13, Week 4	99999	99999	99999	99999
Par 13, Day 59	99999	99999	99999	99999
Par 14, Week 4	-0.3	99999	99999	99999
Par 14, Day 57	0.3	99999	99999	99999
Par 15, Day 169	-0.5	99999	99999	99999
Par 16, Week 4	99999	-0.1	99999	99999
Par 16, Week 12	99999	0.0	99999	99999
Par 16, Day 112	99999	0.4	99999	99999
Par 17, Week 8	99999	0.1	99999	99999
Par 17, Day 85	99999	0.2	99999	99999

End point values	PartB:SIR 50 mg SC q4w+6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Scores on scale				
number (not applicable)				
Par 1, Day 30	99999			
Par 2, Day 29	99999			
Par 3, Day 23	99999			
Par 3, Week 12	99999			
Par 4, Day 113	99999			
Par 5, Week 4	99999			
Par 5, Day 85	99999			
Par 6, Week 4	99999			
Par 6, Day 65	99999			
Par 7, Week 4	99999			
Par 7, Week 8	99999			
Par 7, Week 12	99999			
Par 7, Week 16	99999			

Par 7, Week 36	99999			
Par 7, Day 373	99999			
Par 8, Week 4	99999			
Par 8, Day 64	99999			
Par 9, Day 29	99999			
Par 10, Week 4	99999			
Par 10, Day 57	99999			
Par 11, Week 12	0.9			
Par 11, Week 16	0.9			
Par 11, Day 163	0.4			
Par 12, Week 4	-0.1			
Par 12, Week 8	0.1			
Par 12, Day 85	-0.1			
Par 13, Week 4	-0.6			
Par 13, Day 59	-0.3			
Par 14, Week 4	99999			
Par 14, Day 57	99999			
Par 15, Day 169	99999			
Par 16, Week 4	99999			
Par 16, Week 12	99999			
Par 16, Day 112	99999			
Par 17, Week 8	99999			
Par 17, Day 85	99999			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of participants with PGIC Score over time who received at least one dose of 100 mg OL Sirukumab in Part B

End point title	Part B: Number of participants with PGIC Score over time who received at least one dose of 100 mg OL Sirukumab in Part B
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End point description:

Patient-reported response to treatment was assessed using the PGIC measure, a single item completed by participant to provide a clinically meaningful summary of an individual's response to treatment. The assessment provides an estimate of the magnitude of treatment response at different time points during the study. Responses include: Much Better, Better, Slightly Better, No Change, Slightly Worse, Worse, and Much Worse. The categorical data of participant rating of change is summarized by treatment group, visit and response category.

End point type	Secondary
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End point timeframe:

Baseline (Day 1), Days 103 and 271

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Participants				
number (not applicable)				
Par 1, Day 1: Much Better	1	99999	99999	99999
Par 2, Day 1: Much Better	1	99999	99999	99999
Par 2, Day 271: Worse	1	99999	99999	99999
Par 3, Day 1: Much Better	99999	99999	1	99999
Par 4, Day 1: Much Better	99999	1	99999	99999
Par 5,Day 1: Slightly Better	99999	99999	99999	1
Par 5, Day 103: No change	99999	99999	99999	1
Par 6, Day 1: Better	99999	99999	99999	1
Par 7, Day 1: Much Better	99999	99999	99999	99999
Par 8, Day 1: Slightly Better	99999	99999	99999	99999

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Participants				
number (not applicable)				
Par 1, Day 1: Much Better	99999			
Par 2, Day 1: Much Better	99999			
Par 2, Day 271: Worse	99999			
Par 3, Day 1: Much Better	99999			
Par 4, Day 1: Much Better	99999			
Par 5,Day 1: Slightly Better	99999			
Par 5, Day 103: No change	99999			
Par 6, Day 1: Better	99999			
Par 7, Day 1: Much Better	1			
Par 8, Day 1: Slightly Better	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of participants with PGIC Score over time who never received 100 mg OL Sirukumab in Part B

End point title	Part B: Number of participants with PGIC Score over time who never received 100 mg OL Sirukumab in Part B
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End point description:

Patient-reported response to treatment was assessed using the PGIC measure, a single item completed by participant to provide a clinically meaningful summary of an individual's response to treatment. The

assessment provides an estimate of the magnitude of treatment response at different time points during the study. Responses include: Much Better, Better, Slightly Better, No Change, Slightly Worse, Worse, and Much Worse. The categorical data of participant rating of change is summarized by treatment group, visit and response category.

End point type	Secondary
End point timeframe:	
Baseline (Day 1)	

End point values	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Participants				
number (not applicable)				
Par 1, Day 1: No change	99999	1	99999	99999
Par 2, Day 1: Much Better	99999	1	99999	99999
Par 3, Day 1: Much Better	99999	1	99999	99999
Par 4, Day 1: Much Better	99999	1	99999	99999
Par 5, Day 1: Better	99999	1	99999	99999
Par 6, Day 1: Much Better	99999	1	99999	99999
Par 7, Day 1: Much Better	99999	99999	1	99999
Par 8, Day 1: Better	99999	99999	1	99999
Par 9, Day 1: Much Better	99999	99999	1	99999
Par 10, Day 1: Better	99999	99999	1	99999
Par 11, Day 1: Much Better	99999	99999	99999	1
Par 12, Day 1: Much Better	99999	99999	99999	1
Par 13, Day 1: Better	99999	99999	99999	1
Par 14, Day 1: Better	99999	99999	99999	99999
Par 15, Day 1: Much Better	99999	99999	99999	99999
Par 16, Day 1: Much Better	99999	99999	99999	99999
Par 17, Day 1: Much Better	1	99999	99999	99999
Par 18, Day 1: Much Better	1	99999	99999	99999

End point values	PartB:Placebo SC q2w + 6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Participants				
number (not applicable)				
Par 1, Day 1: No change	99999			
Par 2, Day 1: Much Better	99999			
Par 3, Day 1: Much Better	99999			
Par 4, Day 1: Much Better	99999			
Par 5, Day 1: Better	99999			
Par 6, Day 1: Much Better	99999			

Par 7, Day 1: Much Better	99999			
Par 8, Day 1: Better	99999			
Par 9, Day 1: Much Better	99999			
Par 10, Day 1: Better	99999			
Par 11, Day 1: Much Better	99999			
Par 12, Day 1: Much Better	99999			
Par 13, Day 1: Better	99999			
Par 14, Day 1: Better	1			
Par 15, Day 1: Much Better	1			
Par 16, Day 1: Much Better	1			
Par 17, Day 1: Much Better	99999			
Par 18, Day 1: Much Better	99999			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in CRP over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in CRP over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B
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End point description:

Blood samples were collected for analysis of CRP. Data for Change from Baseline in serum CRP over time for part B was reported. Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Day 0), Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Milligram per liter (mg/L)				
arithmetic mean (standard deviation)				
Week 2, n=1,1,0,1,2	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 4, n=2,1,1,2,2	99999 (± 0.000)	99999 (± 99999)	99999 (± 99999)	99999 (± 1.909)
Week 8, n=2,1,1,2,1	99999 (± 0.000)	99999 (± 99999)	99999 (± 99999)	99999 (± 6.010)
Week 12, n=2,1,1,1,0	99999 (± 0.000)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 14, n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 16, n=2,0,0,1,0	99999 (± 0.424)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Week 24, n=2,0,0,0,0	99999 (± 2.546)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 36, n=2,0,0,0,0	99999 (± 0.849)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 38, n=1,0,0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 40, n=1,0,0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Milligram per liter (mg/L)				
arithmetic mean (standard deviation)				
Week 2, n=1,1,0,1,2	99999 (± 2.970)			
Week 4, n=2,1,1,2,2	99999 (± 2.828)			
Week 8, n=2,1,1,2,1	99999 (± 99999)			
Week 12, n=2,1,1,1,0	99999 (± 99999)			
Week 14, n=0,0,0,1,0	99999 (± 99999)			
Week 16, n=2,0,0,1,0	99999 (± 99999)			
Week 24, n=2,0,0,0,0	99999 (± 99999)			
Week 36, n=2,0,0,0,0	99999 (± 99999)			
Week 38, n=1,0,0,0,0	99999 (± 99999)			
Week 40, n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in CRP over time for participants who never received 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in CRP over time for participants who never received 100 mg OL Sirukumab in Part B
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End point description:

Blood samples were collected for analysis of CRP. Data for Change from Baseline in serum CRP over time for part B was reported. Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Day 0), Weeks 4, 8, 12, 16, 24 and 36

End point values	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: mg/L				
arithmetic mean (standard deviation)				
Week 4, n=3,3,2,1,2	99999 (± 1.202)	99999 (± 0.361)	99999 (± 0.252)	99999 (± 0.071)
Week 8, n=2,1,2,0,2	99999 (± 0.636)	99999 (± 0.778)	99999 (± 99999)	99999 (± 0.000)
Week 12, n=1,1,1,1,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 16, n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 24, n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 36, n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: mg/L				
arithmetic mean (standard deviation)				
Week 4, n=3,3,2,1,2	99999 (± 99999)			
Week 8, n=2,1,2,0,2	99999 (± 99999)			
Week 12, n=1,1,1,1,1	99999 (± 99999)			
Week 16, n=0,1,1,1,0	99999 (± 99999)			
Week 24, n=0,1,0,0,0	99999 (± 99999)			
Week 36, n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in ESR over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in ESR over time for participants
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End point description:

Blood samples were collected for analysis of ESR. Data for Change from Baseline in ESR over time for part A was reported. Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type Secondary

End point timeframe:

Baseline (Day 0), Weeks 2, 4, 8, 12, 14, 16, 24, 36, 38 and 40

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Millimeter per hour (mm/h)				
arithmetic mean (standard deviation)				
Week 2, n=1,1,0,1,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 4, n=2,1,1,2,2	99999 (± 2.12)	99999 (± 99999)	99999 (± 99999)	99999 (± 16.97)
Week 8, n=2,1,0,2,1	99999 (± 7.07)	99999 (± 99999)	99999 (± 99999)	99999 (± 15.56)
Week 12, n=2,1,1,1,0	99999 (± 1.41)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 14, n=0,0,0,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 16, n=2,0,0,1,0	99999 (± 2.12)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 24, n=2,0,0,0,0	(± 0.71)	(± 99999)	(± 99999)	(± 99999)
Week 36, n=2,0,0,0,0	99999 (± 11.31)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 38, n=1,0,0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 40, n=1,0,0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Millimeter per hour (mm/h)				
arithmetic mean (standard deviation)				
Week 2, n=1,1,0,1,1	99999 (± 99999)			
Week 4, n=2,1,1,2,2	99999 (± 31.82)			
Week 8, n=2,1,0,2,1	99999 (± 99999)			

Week 12, n=2,1,1,1,0	99999 (± 99999)			
Week 14, n=0,0,0,1,0	99999 (± 99999)			
Week 16, n=2,0,0,1,0	99999 (± 99999)			
Week 24, n=2,0,0,0,0	(± 99999)			
Week 36, n=2,0,0,0,0	99999 (± 99999)			
Week 38, n=1,0,0,0,0	99999 (± 99999)			
Week 40, n=1,0,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in ESR over time for participants who never received 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in ESR over time for participants who never received 100 mg OL Sirukumab in Part B
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End point description:

Blood samples were collected for analysis of ESR. Data for Change from Baseline in ESR over time for part A was reported. Baseline was the last measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Day 0), Weeks 4, 8, 12, 16, 24 and 36

End point values	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: mm/h				
arithmetic mean (standard deviation)				
Week 36, n=0,1,0,0,0	99999 (± 99999)	99999 (± 5.03)	99999 (± 99999)	99999 (± 99999)
Week 4, n=3,3,3,1,2	99999 (± 5.66)	99999 (± 5.03)	99999 (± 1.53)	99999 (± 1.00)
Week 8, n=2,1,3,0,2	99999 (± 2.83)	99999 (± 7.07)	99999 (± 99999)	99999 (± 0.00)
Week 12, n=1,1,1,1,1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 16, n=0,1,1,1,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Week 24, n=0,1,0,0,0	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	PartB:Placebo SC q2w + 6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: mm/h				
arithmetic mean (standard deviation)				
Week 36, n=0,1,0,0,0	99999 (± 99999)			
Week 4, n=3,3,3,1,2	99999 (± 99999)			
Week 8, n=2,1,3,0,2	99999 (± 99999)			
Week 12, n=1,1,1,1,1	99999 (± 99999)			
Week 16, n=0,1,1,1,0	99999 (± 99999)			
Week 24, n=0,1,0,0,0	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in EQ-5D-5L VAS over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in EQ-5D-5L VAS over time for participants who received at least one dose of 100 mg OL Sirukumab in Part B
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End point description:

EQ-5D essentially consists of 2 elements: the EQ-5D descriptive system and the EQ VAS. The EQ-5D descriptive system comprised of the following 6 dimensions: 1.Mobility, 2.Self, 3.Usual Activities, 4.Pain/Discomfort, 5.Anxiety/Depression; 6.How good or or bad your health is today. Each of these 6 dimensions has 5 levels: 1: no problems; 2: slight problems; 3: moderate problems; 4: severe problems; 5: Unable to do. The EQ VAS records the respondent's self-rated health on a vertical line, VAS where the endpoints are 'Best imaginable health state' and 'Worst imaginable health state'. Answers to 'How good or bad your health is today' were measured on a 100 point VAS scale. Baseline for Part B is the last non-missing measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Day 0) and Days 85, 87, 91, 113, 162, 339 and 344 and Weeks 12 and 24

End point values	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:Placebo SC q2w + 6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	1	1	2
Units: Scores on scale				
number (not applicable)				
Par 2, Day 344	-1	99999	99999	99999
Par 3, Day 113	99999	99999	1	99999
Par 4, Week 12	99999	-4	99999	99999
Par 5, Week 12	99999	99999	99999	9
Par 5, Day 162	99999	99999	99999	-15
Par 6, Day 91	99999	99999	99999	20
Par 7, Day 85	99999	99999	99999	99999
Par 8, Day 87	99999	99999	99999	99999
Par 1, Week 12	-12	99999	99999	99999
Par 1, Week 24	1	99999	99999	99999
Par 1, Day 339	8	99999	99999	99999
Par 2, Week 12	3	99999	99999	99999
Par 2, Week 24	14	99999	99999	99999

End point values	PartB:Placebo SC q2w + 12 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: Scores on scale				
number (not applicable)				
Par 2, Day 344	99999			
Par 3, Day 113	99999			
Par 4, Week 12	99999			
Par 5, Week 12	99999			
Par 5, Day 162	99999			
Par 6, Day 91	99999			
Par 7, Day 85	4			
Par 8, Day 87	21			
Par 1, Week 12	99999			
Par 1, Week 24	99999			
Par 1, Day 339	99999			
Par 2, Week 12	99999			
Par 2, Week 24	99999			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in EQ-5D-5L VAS over time for participants who never received 100 mg OL Sirukumab in Part B

End point title	Part B: Change from Baseline in EQ-5D-5L VAS over time for participants who never received 100 mg OL Sirukumab in Part B
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End point description:

EQ-5D essentially consists of 2 elements: the EQ-5D descriptive system and the EQ VAS. The EQ-5D descriptive system comprised of the following 6 dimensions: 1.Mobility, 2.Self, 3.Usual Activities, 4.Pain/Discomfort, 5.Anxiety/Depression; 6.How good or or bad your health is today. Each of these 6 dimensions has 5 levels: 1: no problems; 2: slight problems; 3: moderate problems; 4: severe problems; 5: Unable to do. The EQ VAS records the respondent's self-rated health on a vertical line, VAS where the endpoints are 100 (Best imaginable health state) and 0 (Worst imaginable health state). Answers to 'How good or bad your health is today' were measured on a 100 point VAS scale. Baseline for Part B is the last non-missing measurement done up to and including the Week 52 visit date of Part A. Change from Baseline was defined as post-Baseline value minus Baseline value.

End point type	Secondary
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End point timeframe:

Baseline (Day 0) and Days 23, 29, 30, 57, 59, 64, 65, 85, 112, 113, 163, 169, 344 and 373 and Week 12

End point values	PartB:Placebo SC q2w + 12 month prednisone	PartB:SIR 100 mg SC q2w+6 month prednisone	PartB:SIR 100 mg SC q2w+3 month prednisone	PartB:SIR 50 mg SC q4w+6 month prednisone
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	6	4	3
Units: Scores on scale				
number (not applicable)				
Par 5, Day 85	99999	-1	99999	99999
Par 6, Day 65	99999	20	99999	99999
Par 7, Week 12	99999	99999	4	99999
Par 7, Day 373	99999	99999	8	99999
Par 8, Day 64	99999	99999	-2	99999
Par 9, Day 29	99999	99999	-1	99999
Par 10, Day 57	99999	99999	5	99999
Par 11, Week 12	99999	99999	99999	-10
Par 11, Day 163	99999	99999	99999	-12
Par 12, Day 85	99999	99999	99999	-8
Par 13, Day 59	99999	99999	99999	10
Par 14, Day 57	99999	99999	99999	99999
Par 16, Day 169	99999	99999	99999	99999
Par 17, Week 12	9	99999	99999	99999
Par 17, Day 112	7	99999	99999	99999
Par 18, Day 85	-4	99999	99999	99999
Par 1, Day 30	99999	2	99999	99999
Par 2, Day 29	99999	0	99999	99999
Par 3, Day 23	99999	1	99999	99999
Par 4, Week 12	99999	-2	99999	99999
Par 4, Day 113	99999	-47	99999	99999

End point values	PartB:Placebo SC q2w + 6 month prednisone			
Subject group type	Subject analysis set			
Number of subjects analysed	3			
Units: Scores on scale				
number (not applicable)				
Par 5, Day 85	99999			
Par 6, Day 65	99999			
Par 7, Week 12	99999			
Par 7, Day 373	99999			
Par 8, Day 64	99999			
Par 9, Day 29	99999			
Par 10, Day 57	99999			
Par 11, Week 12	99999			
Par 11, Day 163	99999			
Par 12, Day 85	99999			
Par 13, Day 59	99999			
Par 14, Day 57	-42			
Par 16, Day 169	62			
Par 17, Week 12	99999			
Par 17, Day 112	99999			
Par 18, Day 85	99999			
Par 1, Day 30	99999			
Par 2, Day 29	99999			
Par 3, Day 23	99999			
Par 4, Week 12	99999			
Par 4, Day 113	99999			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On-treatment serious Adverse events (SAEs) and non-serious Adverse Events (nSAEs) were collected from the start of study treatment up to Week 52 in Part A and up to Week 104 in Part B.

Adverse event reporting additional description:

Safety Set was used. Safety Population comprised of all randomized participants who received at least 1 dose of SC Investigational Product.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.1
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Reporting groups

Reporting group title	Part A:SIR 100 mg SC q2w+6 month prednisone
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Reporting group description:

Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen

Reporting group title	Part A:SIR 100 mg SC q2w+3 month prednisone
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Reporting group description:

Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen

Reporting group title	Part A: SIR 50 mg SC q4w+6 month prednisone
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Reporting group description:

Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen

Reporting group title	Part A:Placebo SC q2w + 6 month prednisone
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Reporting group description:

Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen

Reporting group title	Part A:Placebo SC q2w + 12 month prednisone
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Reporting group description:

Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen

Reporting group title	Part B:SIR 100 mg SC q2w+6 month Prednisone+100mg OL SIR
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Reporting group description:

Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen in Part A. Participants received at least one dose of 100mg OL SIR in Part B.

Reporting group title	Part B:SIR 100 mg SC q2w+3 month Prednisone+100mg OL SIR
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Reporting group description:

Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen in Part A. Participants received at least one dose of 100mg OL SIR in Part B.

Reporting group title	Part B:SIR 50 mg SC q4w+6 month Prednisone+100mg OL SIR
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Reporting group description:

Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen in Part A. Participants received at least one dose of 100mg OL SIR in Part B.

Reporting group title	Part B:Placebo SC q2w + 6 month Prednisone+100mg OL SIR
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Reporting group description:

Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen in Part A. Participants received at least one dose of 100mg OL SIR in Part B.

Reporting group title	Part B:Placebo SC q2w + 12 month Prednisone+100mg OL SIR
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Reporting group description:

Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen in Part A. Participants received at least one dose of 100mg OL SIR in Part B.

Reporting group title	Part B:SIR 100 mg SC q2w+6 month Prednisone/ No 100mg OL SIR
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Reporting group description:

Participants received SIR 100 milligram (mg) subcutaneously (SC) every 2 weeks (q2w) for 52 weeks plus a pre-specified maximum of 6-months prednisone taper regimen in Part A. Participants never received 100mg OL SIR in Part B.

Reporting group title	Part B:SIR 100 mg SC q2w+3 month Prednisone/ No 100mg OL SIR
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Reporting group description:

Participants received SIR 100 mg SC q2w for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen in Part A. Participants never received 100mg OL SIR in Part B.

Reporting group title	Part B:SIR 50 mg SC q4w+6 month Prednisone/ No 100mg OL SIR
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Reporting group description:

Participants received SIR 50 mg SC every 4 weeks (q4w) for 52 weeks plus a pre-specified maximum of 3-month prednisone taper regimen in Part A. Participants never received 100mg OL SIR in Part B.

Reporting group title	Part B:Placebo SC q2w + 6 month Prednisone/ No 100mg OL SIR
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Reporting group description:

Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 6-month prednisone taper regimen in Part A. Participants never received 100mg OL SIR in Part B.

Reporting group title	Part B:Placebo SC q2w + 12 month Prednisone/ No 100mg OL SIR
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Reporting group description:

Participants received placebo SC q2w for 52 weeks plus a pre-specified maximum of 12-month prednisone taper regimen in Part A. Participants never received 100mg OL SIR in Part B.

Serious adverse events	Part A:SIR 100 mg SC q2w+6 month prednisone	Part A:SIR 100 mg SC q2w+3 month prednisone	Part A: SIR 50 mg SC q4w+6 month prednisone
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 42 (19.05%)	6 / 39 (15.38%)	6 / 26 (23.08%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 42 (0.00%)	1 / 39 (2.56%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Temporal arteritis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 42 (0.00%)	1 / 39 (2.56%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 39 (2.56%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchiectasis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Brain contusion			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 42 (0.00%)	1 / 39 (2.56%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	2 / 26 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	0 / 42 (0.00%)	1 / 39 (2.56%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal artery occlusion			
subjects affected / exposed	0 / 42 (0.00%)	1 / 39 (2.56%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Large intestine polyp			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis cholestatic			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Hypersensitivity vasculitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			

subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 39 (2.56%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Clostridium difficile colitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metapneumovirus infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 39 (2.56%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Electrolyte imbalance			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A:Placebo SC q2w + 6 month prednisone	Part A:Placebo SC q2w + 12 month prednisone	Part B:SIR 100 mg SC q2w+6 month Prednisone+100mg OL SIR
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 27 (18.52%)	6 / 27 (22.22%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			

subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Temporal arteritis			
subjects affected / exposed	1 / 27 (3.70%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchiectasis			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Brain contusion			

subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	1 / 27 (3.70%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal artery occlusion			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Large intestine polyp			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis cholestatic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Hypersensitivity vasculitis			

subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	1 / 27 (3.70%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	1 / 27 (3.70%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Clostridium difficile colitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Escherichia sepsis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 27 (3.70%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Electrolyte imbalance			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part B:SIR 100 mg SC q2w+3 month Prednisone+100mg OL SIR	Part B:SIR 50 mg SC q4w+6 month Prednisone+100mg OL SIR	Part B:Placebo SC q2w + 6 month Prednisone+100mg OL SIR
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Temporal arteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchiectasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol withdrawal syndrome			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Brain contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal artery occlusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Large intestine polyp			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis cholestatic			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Hypersensitivity vasculitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations Clostridium difficile colitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 2 (0.00%) 0 / 0 0 / 0
Escherichia sepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 2 (0.00%) 0 / 0 0 / 0
Metapneumovirus infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 2 (0.00%) 0 / 0 0 / 0
Pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 2 (0.00%) 0 / 0 0 / 0
Urinary tract infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 2 (0.00%) 0 / 0 0 / 0
Vestibular neuronitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 2 (0.00%) 0 / 0 0 / 0
Metabolism and nutrition disorders Electrolyte imbalance subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 2 (0.00%) 0 / 0 0 / 0

Serious adverse events	Part B:Placebo SC q2w + 12 month Prednisone+100mg OL SIR	Part B:SIR 100 mg SC q2w+6 month Prednisone/ No 100mg OL SIR	Part B:SIR 100 mg SC q2w+3 month Prednisone/ No 100mg OL SIR
Total subjects affected by serious adverse events			

subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Temporal arteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchiectasis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Brain contusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal artery occlusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Large intestine polyp			

subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis cholestatic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Hypersensitivity vasculitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			

subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Clostridium difficile colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			

Electrolyte imbalance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part B:SIR 50 mg SC q4w+6 month Prednisone/ No 100mg OL SIR	Part B:Placebo SC q2w + 6 month Prednisone/ No 100mg OL SIR	Part B:Placebo SC q2w + 12 month Prednisone/ No 100mg OL SIR
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Temporal arteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchiectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Brain contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal artery occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Large intestine polyp			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis cholestatic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Hypersensitivity vasculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Electrolyte imbalance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Part A:SIR 100 mg SC q2w+6 month prednisone	Part A:SIR 100 mg SC q2w+3 month prednisone	Part A: SIR 50 mg SC q4w+6 month prednisone
Total subjects affected by non-serious adverse events			
subjects affected / exposed	41 / 42 (97.62%)	36 / 39 (92.31%)	25 / 26 (96.15%)
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 42 (9.52%)	2 / 39 (5.13%)	4 / 26 (15.38%)
occurrences (all)	5	3	4
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 42 (7.14%)	1 / 39 (2.56%)	1 / 26 (3.85%)
occurrences (all)	3	2	1
Fatigue			
subjects affected / exposed	2 / 42 (4.76%)	3 / 39 (7.69%)	4 / 26 (15.38%)
occurrences (all)	2	41	5
Injection site erythema			
subjects affected / exposed	9 / 42 (21.43%)	4 / 39 (10.26%)	2 / 26 (7.69%)
occurrences (all)	29	4	5
Injection site pain			

subjects affected / exposed	2 / 42 (4.76%)	3 / 39 (7.69%)	2 / 26 (7.69%)
occurrences (all)	2	3	6
Injection site pruritus			
subjects affected / exposed	3 / 42 (7.14%)	4 / 39 (10.26%)	1 / 26 (3.85%)
occurrences (all)	19	7	2
Injection site reaction			
subjects affected / exposed	6 / 42 (14.29%)	2 / 39 (5.13%)	4 / 26 (15.38%)
occurrences (all)	9	6	13
Injection site swelling			
subjects affected / exposed	4 / 42 (9.52%)	4 / 39 (10.26%)	2 / 26 (7.69%)
occurrences (all)	6	4	8
Injection site warmth			
subjects affected / exposed	1 / 42 (2.38%)	2 / 39 (5.13%)	1 / 26 (3.85%)
occurrences (all)	3	2	1
Oedema peripheral			
subjects affected / exposed	5 / 42 (11.90%)	8 / 39 (20.51%)	3 / 26 (11.54%)
occurrences (all)	5	14	4
Pain			
subjects affected / exposed	1 / 42 (2.38%)	1 / 39 (2.56%)	2 / 26 (7.69%)
occurrences (all)	1	11	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	8 / 42 (19.05%)	2 / 39 (5.13%)	2 / 26 (7.69%)
occurrences (all)	8	3	2
Dyspnoea			
subjects affected / exposed	2 / 42 (4.76%)	2 / 39 (5.13%)	1 / 26 (3.85%)
occurrences (all)	2	8	1
Epistaxis			
subjects affected / exposed	3 / 42 (7.14%)	2 / 39 (5.13%)	2 / 26 (7.69%)
occurrences (all)	4	2	2
Oropharyngeal pain			
subjects affected / exposed	4 / 42 (9.52%)	1 / 39 (2.56%)	4 / 26 (15.38%)
occurrences (all)	4	1	4
Rhinorrhoea			

subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	2 / 26 (7.69%) 2
Psychiatric disorders			
Insomnia			
subjects affected / exposed	3 / 42 (7.14%)	2 / 39 (5.13%)	2 / 26 (7.69%)
occurrences (all)	3	4	2
Nervousness			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
Investigations			
C-reactive protein abnormal			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	2 / 26 (7.69%)
occurrences (all)	1	0	2
Platelet count decreased			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	2 / 26 (7.69%)
occurrences (all)	1	0	2
Alanine aminotransferase increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	1 / 42 (2.38%)	1 / 39 (2.56%)	2 / 26 (7.69%)
occurrences (all)	1	1	2
Contusion			
subjects affected / exposed	3 / 42 (7.14%)	1 / 39 (2.56%)	2 / 26 (7.69%)
occurrences (all)	4	1	2
Fall			
subjects affected / exposed	4 / 42 (9.52%)	2 / 39 (5.13%)	0 / 26 (0.00%)
occurrences (all)	8	2	0
Joint dislocation			

subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	4 / 42 (9.52%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	5	0	0
Road traffic accident			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Limb traumatic amputation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 42 (7.14%)	4 / 39 (10.26%)	2 / 26 (7.69%)
occurrences (all)	3	5	3
Headache			
subjects affected / exposed	13 / 42 (30.95%)	7 / 39 (17.95%)	8 / 26 (30.77%)
occurrences (all)	20	14	16
Hypoaesthesia			
subjects affected / exposed	1 / 42 (2.38%)	2 / 39 (5.13%)	0 / 26 (0.00%)
occurrences (all)	1	3	0

Paraesthesia subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	2 / 39 (5.13%) 2	0 / 26 (0.00%) 0
Tremor subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 3	3 / 39 (7.69%) 3	1 / 26 (3.85%) 1
Syncope subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	0 / 26 (0.00%) 0
Blood and lymphatic system disorders Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	4 / 39 (10.26%) 5	1 / 26 (3.85%) 1
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	1 / 39 (2.56%) 1	2 / 26 (7.69%) 3
Eye disorders Blepharitis subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	2 / 39 (5.13%) 2	0 / 26 (0.00%) 0
Cataract subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	1 / 39 (2.56%) 1	1 / 26 (3.85%) 1
Eye pain subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	0 / 39 (0.00%) 0	1 / 26 (3.85%) 1
Chalazion subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	0 / 26 (0.00%) 0
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	2 / 39 (5.13%) 2	3 / 26 (11.54%) 3
Abdominal pain upper subjects affected / exposed occurrences (all)	2 / 42 (4.76%) 2	2 / 39 (5.13%) 4	2 / 26 (7.69%) 3

Diarrhoea			
subjects affected / exposed	5 / 42 (11.90%)	2 / 39 (5.13%)	5 / 26 (19.23%)
occurrences (all)	5	2	12
Faeces discoloured			
subjects affected / exposed	0 / 42 (0.00%)	2 / 39 (5.13%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
Gastritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 42 (0.00%)	1 / 39 (2.56%)	2 / 26 (7.69%)
occurrences (all)	0	1	2
Haemorrhoids			
subjects affected / exposed	0 / 42 (0.00%)	2 / 39 (5.13%)	0 / 26 (0.00%)
occurrences (all)	0	3	0
Nausea			
subjects affected / exposed	3 / 42 (7.14%)	2 / 39 (5.13%)	2 / 26 (7.69%)
occurrences (all)	4	2	2
Toothache			
subjects affected / exposed	4 / 42 (9.52%)	1 / 39 (2.56%)	1 / 26 (3.85%)
occurrences (all)	4	1	1
Abdominal hernia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Noninfective gingivitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0

Abdominal distension subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	2 / 26 (7.69%) 2
Skin and subcutaneous tissue disorders			
Alopecia subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 3	2 / 39 (5.13%) 2	2 / 26 (7.69%) 2
Hyperhidrosis subjects affected / exposed occurrences (all)	5 / 42 (11.90%) 5	1 / 39 (2.56%) 5	1 / 26 (3.85%) 1
Night sweats subjects affected / exposed occurrences (all)	2 / 42 (4.76%) 2	1 / 39 (2.56%) 1	2 / 26 (7.69%) 2
Pruritus subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	0 / 39 (0.00%) 0	2 / 26 (7.69%) 2
Swelling face subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	1 / 39 (2.56%) 1	2 / 26 (7.69%) 2
Macule subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	0 / 26 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	0 / 26 (0.00%) 0
Purpura subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	0 / 26 (0.00%) 0
Endocrine disorders			
Cushingoid subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	2 / 39 (5.13%) 2	0 / 26 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	5 / 42 (11.90%) 7	4 / 39 (10.26%) 36	5 / 26 (19.23%) 6

Back pain			
subjects affected / exposed	7 / 42 (16.67%)	3 / 39 (7.69%)	3 / 26 (11.54%)
occurrences (all)	7	9	5
Bursitis			
subjects affected / exposed	1 / 42 (2.38%)	2 / 39 (5.13%)	0 / 26 (0.00%)
occurrences (all)	1	2	0
Muscle spasms			
subjects affected / exposed	3 / 42 (7.14%)	5 / 39 (12.82%)	3 / 26 (11.54%)
occurrences (all)	6	6	3
Muscular weakness			
subjects affected / exposed	1 / 42 (2.38%)	3 / 39 (7.69%)	0 / 26 (0.00%)
occurrences (all)	1	4	0
Musculoskeletal chest pain			
subjects affected / exposed	2 / 42 (4.76%)	2 / 39 (5.13%)	2 / 26 (7.69%)
occurrences (all)	2	3	2
Musculoskeletal pain			
subjects affected / exposed	3 / 42 (7.14%)	2 / 39 (5.13%)	1 / 26 (3.85%)
occurrences (all)	3	7	2
Myalgia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 39 (2.56%)	2 / 26 (7.69%)
occurrences (all)	0	1	2
Neck pain			
subjects affected / exposed	1 / 42 (2.38%)	2 / 39 (5.13%)	1 / 26 (3.85%)
occurrences (all)	2	5	1
Osteoarthritis			
subjects affected / exposed	2 / 42 (4.76%)	1 / 39 (2.56%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
Pain in extremity			
subjects affected / exposed	3 / 42 (7.14%)	2 / 39 (5.13%)	3 / 26 (11.54%)
occurrences (all)	3	6	5
Pain in jaw			
subjects affected / exposed	3 / 42 (7.14%)	2 / 39 (5.13%)	0 / 26 (0.00%)
occurrences (all)	3	3	0
Polymyalgia rheumatica			
subjects affected / exposed	1 / 42 (2.38%)	1 / 39 (2.56%)	0 / 26 (0.00%)
occurrences (all)	1	1	0

Synovial cyst subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	0 / 26 (0.00%) 0
Intervertebral disc protrusion subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	0 / 26 (0.00%) 0
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	3 / 39 (7.69%) 3	0 / 26 (0.00%) 0
Gastroenteritis subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	2 / 39 (5.13%) 2	2 / 26 (7.69%) 2
Nasopharyngitis subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 3	2 / 39 (5.13%) 2	3 / 26 (11.54%) 4
Onychomycosis subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	2 / 39 (5.13%) 3	0 / 26 (0.00%) 0
Oral herpes subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	2 / 39 (5.13%) 2	1 / 26 (3.85%) 1
Rhinitis subjects affected / exposed occurrences (all)	1 / 42 (2.38%) 1	0 / 39 (0.00%) 0	2 / 26 (7.69%) 2
Sinusitis subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 3	3 / 39 (7.69%) 3	2 / 26 (7.69%) 2
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 42 (4.76%) 2	8 / 39 (20.51%) 8	2 / 26 (7.69%) 2
Urinary tract infection subjects affected / exposed occurrences (all)	3 / 42 (7.14%) 4	2 / 39 (5.13%) 2	2 / 26 (7.69%) 2
Viral upper respiratory tract infection			

subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	0 / 26 (0.00%) 0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	0 / 26 (0.00%) 0
Gout			
subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	0 / 26 (0.00%) 0
Vitamin D deficiency			
subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	0 / 39 (0.00%) 0	0 / 26 (0.00%) 0

Non-serious adverse events	Part A:Placebo SC q2w + 6 month prednisone	Part A:Placebo SC q2w + 12 month prednisone	Part B:SIR 100 mg SC q2w+6 month Prednisone+100mg OL SIR
Total subjects affected by non-serious adverse events subjects affected / exposed	26 / 27 (96.30%)	24 / 27 (88.89%)	2 / 2 (100.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	1 / 27 (3.70%) 2	0 / 2 (0.00%) 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1	2 / 27 (7.41%) 2	0 / 2 (0.00%) 0
Fatigue			
subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 2	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Injection site erythema			
subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	1 / 2 (50.00%) 1
Injection site pain			
subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Injection site pruritus			

subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	3
Injection site reaction			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Injection site swelling			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Injection site warmth			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 27 (7.41%)	3 / 27 (11.11%)	0 / 2 (0.00%)
occurrences (all)	3	5	0
Dyspnoea			
subjects affected / exposed	0 / 27 (0.00%)	2 / 27 (7.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Epistaxis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Insomnia			
subjects affected / exposed	1 / 27 (3.70%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Nervousness			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
C-reactive protein abnormal			
subjects affected / exposed	2 / 27 (7.41%)	0 / 27 (0.00%)	1 / 2 (50.00%)
occurrences (all)	3	0	1
Low density lipoprotein increased			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	2 / 27 (7.41%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Fall			
subjects affected / exposed	0 / 27 (0.00%)	3 / 27 (11.11%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Joint dislocation			
subjects affected / exposed	0 / 27 (0.00%)	2 / 27 (7.41%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Ligament sprain			

subjects affected / exposed	2 / 27 (7.41%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Limb injury			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 27 (0.00%)	2 / 27 (7.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Tendon rupture			
subjects affected / exposed	0 / 27 (0.00%)	2 / 27 (7.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Foot fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Laceration			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Limb traumatic amputation			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 27 (3.70%)	3 / 27 (11.11%)	1 / 2 (50.00%)
occurrences (all)	1	3	1
Headache			
subjects affected / exposed	7 / 27 (25.93%)	8 / 27 (29.63%)	0 / 2 (0.00%)
occurrences (all)	7	13	0
Hypoaesthesia			
subjects affected / exposed	1 / 27 (3.70%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
Paraesthesia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Tremor subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Syncope subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Blood and lymphatic system disorders Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Eye disorders Blepharitis subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Cataract subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1	2 / 27 (7.41%) 3	0 / 2 (0.00%) 0
Eye pain subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	2 / 27 (7.41%) 2	0 / 2 (0.00%) 0
Chalazion subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 3	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0

Faeces discoloured			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	2 / 27 (7.41%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 27 (7.41%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Haemorrhoids			
subjects affected / exposed	1 / 27 (3.70%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	0 / 27 (0.00%)	2 / 27 (7.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Toothache			
subjects affected / exposed	2 / 27 (7.41%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Abdominal hernia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Noninfective gingivitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	1 / 27 (3.70%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	1 / 27 (3.70%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 27 (3.70%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Swelling face			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 27 (0.00%)	2 / 27 (7.41%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	1 / 27 (3.70%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 27 (3.70%)	4 / 27 (14.81%)	0 / 2 (0.00%)
occurrences (all)	1	6	0
Back pain			
subjects affected / exposed	2 / 27 (7.41%)	4 / 27 (14.81%)	0 / 2 (0.00%)
occurrences (all)	2	5	0

Bursitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 27 (3.70%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Muscular weakness			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 27 (3.70%)	0 / 27 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	2 / 27 (7.41%)	4 / 27 (14.81%)	0 / 2 (0.00%)
occurrences (all)	2	5	0
Myalgia			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	0 / 27 (0.00%)	2 / 27 (7.41%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Pain in extremity			
subjects affected / exposed	2 / 27 (7.41%)	3 / 27 (11.11%)	0 / 2 (0.00%)
occurrences (all)	2	3	0
Pain in jaw			
subjects affected / exposed	0 / 27 (0.00%)	1 / 27 (3.70%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Polymyalgia rheumatica			
subjects affected / exposed	1 / 27 (3.70%)	2 / 27 (7.41%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Synovial cyst			
subjects affected / exposed	0 / 27 (0.00%)	0 / 27 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1

Intervertebral disc protrusion subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 2	1 / 27 (3.70%) 1	0 / 2 (0.00%) 0
Gastroenteritis subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1	1 / 27 (3.70%) 1	0 / 2 (0.00%) 0
Onychomycosis subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	1 / 27 (3.70%) 1	0 / 2 (0.00%) 0
Oral herpes subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Rhinitis subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Sinusitis subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	4 / 27 (14.81%) 5	1 / 27 (3.70%) 1	0 / 2 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 2	4 / 27 (14.81%) 10	0 / 2 (0.00%) 0
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Metabolism and nutrition disorders			

Hypercholesterolaemia subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0
Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	0 / 2 (0.00%) 0

Non-serious adverse events	Part B:SIR 100 mg SC q2w+3 month Prednisone+100mg OL SIR	Part B:SIR 50 mg SC q4w+6 month Prednisone+100mg OL SIR	Part B:Placebo SC q2w + 6 month Prednisone+100mg OL SIR
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 1 (100.00%)	1 / 1 (100.00%)	2 / 2 (100.00%)
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Injection site erythema subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Injection site pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Injection site pruritus subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Injection site reaction			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site warmth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervousness			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Investigations			
C-reactive protein abnormal subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Low density lipoprotein increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Joint dislocation subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Ligament sprain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Limb injury			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Limb traumatic amputation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Hypoaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Syncope subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Blood and lymphatic system disorders Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Eye disorders Blepharitis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Cataract subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Eye pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Chalazion subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Faeces discoloured subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0

Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	3
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Eructation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Noninfective gingivitis			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Swelling face			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Purpura			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bursitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B:Placebo SC q2w + 12 month Prednisone+100mg OL SIR	Part B:SIR 100 mg SC q2w+6 month Prednisone/ No 100mg OL SIR	Part B:SIR 100 mg SC q2w+3 month Prednisone/ No 100mg OL SIR
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	4 / 6 (66.67%)	3 / 4 (75.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Injection site swelling subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Injection site warmth subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Nervousness subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Investigations			

C-reactive protein abnormal subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Low density lipoprotein increased subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Joint dislocation subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Ligament sprain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Limb injury subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Road traffic accident			

subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb traumatic amputation			
subjects affected / exposed	1 / 2 (50.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Blood and lymphatic system disorders Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Eye disorders Blepharitis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Cataract subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Eye pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Chalazion subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Faeces discoloured subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0

Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Abdominal hernia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Eruption subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 2	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Noninfective gingivitis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Rectal haemorrhage subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	1 / 4 (25.00%) 1
Dyspepsia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Hyperhidrosis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	1 / 2 (50.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Purpura			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			

subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 2 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Synovial cyst			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Onychomycosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 2 (50.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 2 (50.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gout			

subjects affected / exposed	0 / 2 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Part B:SIR 50 mg SC q4w+6 month Prednisone/ No 100mg OL SIR	Part B:Placebo SC q2w + 6 month Prednisone/ No 100mg OL SIR	Part B:Placebo SC q2w + 12 month Prednisone/ No 100mg OL SIR
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	0 / 2 (0.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Injection site warmth subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Nervousness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Investigations			
C-reactive protein abnormal subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0

Low density lipoprotein increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Joint dislocation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Ligament sprain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Limb injury subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Road traffic accident subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Tendon rupture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Limb traumatic amputation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Thrombocytopenia			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Eye disorders Blepharitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Cataract subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Eye pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Chalazion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Faeces discoloured subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Noninfective gingivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Onychomycosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 October 2015	Amendment No. 1: Protocol has been updated to clarify the secondary objectives and endpoints of characterization of sustained remission in Parts A and B, collection of patient and physician reported outcomes, including correction of the version of the EQ-5D version that will be administered and pain assessment using a numeric rating scale. Further clarifications have been included in updates to the potential signs and symptoms of GCA, prednisone use during screening and taper initiation, participant eligibility for receiving open-label sirukumab in Part B and investigator consideration of the individual participant benefit-risk of continuing sirukumab in Part B. This amendment includes additional information on risk mitigation for GI perforations and serious allergic/hypersensitivity events. The inclusion criteria for GCA diagnostic criteria for temporal artery biopsy and imaging and symptoms of active GCA have been updated. Other changes include removal of restrictions on the use of NSAIDs, clarification of circumstances requiring discontinuation of study treatment but not study withdrawal, and circumstances in which subjects may withdraw from the study. The Time and Events table has been updated and corrections included. Other additions include guidance to investigators related to treatment of glucocorticoid-induced osteoporosis. Clarification of protocol-specified exploratory biomarkers and optional exploratory biomarkers, updated information on the study number for the exploratory imaging sub-study, randomization system and correction of typographical errors.
31 March 2016	Amendment No. 2: Amendment has been updated to include the assessment of the utility of ultrasound imaging as an indicator of disease activity in an exploratory cohort of participants. Other modifications include updates to the inclusion criteria for diagnosis of GCA to allow for diagnosis by ultrasound imaging in sites qualified to participate in the ultrasound imaging portion of the study, to further clarify features consistent with GCA or PMR flares, and to clarify requirements for the prednisone dose at Screening. The inclusion criteria have also been amended to include the acceptability of a single view of chest radiographs if consistent with local guidelines. Updated information on the pre-filled syringes has been included. Other modifications include the clarification that the daily prednisone dose should be taken in a single daily administration in the morning. Country-specific requirements have been included for Germany, the Netherlands, and Australia and New Zealand. These include a requirement to discontinue study drug administration in the event of a serious infection (Germany), a requirement for participants to discontinue the study at the conclusion of Part A after completing the 16-week follow up phase (the Netherlands) and a requirement to notify investigators when the value of the ESR result is > 40 mm/hr or has increased > 10 mm/hr from baseline or previous result (Australia and New Zealand).
17 November 2016	Amendment No. 3: Amendment has been updated to include the implementation of the Columbia-Suicide Severity Rating Scale to prospectively monitor suicidal ideation and behavior. Other modifications include revision of the endpoints for the exploratory imaging cohort, further clarifications regarding the initiation of the prednisone taper and prednisone sourcing information, and inclusion of malignancies as a potential risk of clinical significance. In addition, a requirement for male contraception and restrictions on sperm donation, amendment of QTc exclusion and stopping criteria, revision of criteria to allow prior anti-IL-6 use if not associated with intolerance or inadequate response, and addition of an exclusion criterion related to suicidality are included. Pregnancy testing is now required at 4-weekly intervals while participants are receiving study drug during Parts A and B and during the 16-week follow up period after drug discontinuation. Additional clarification of reflex testing for hepatitis and tuberculosis testing have been included. Updated information regarding database locks and unblinding and treatment comparisons has also been included.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported