Clinical trial results:
A MULTI-CENTER, RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP, DOSE RANGING STUDY FOLLOWED BY AN OBSERVATIONAL PERIOD TO EVALUATE THE EFFICACY AND SAFETY OF DAPIROLIZUMAB PEGOL IN SUBJECTS WITH MODERATELY TO SEVERELY ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS

Summary

EudraCT number	2015-004457-40
Trial protocol	DE RO HU BG ES PL
Global end of trial date	15 November 2018

Results information

Result version number	v2 (current)
This version publication date	26 July 2021
First version publication date	02 December 2019
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	SL0023

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02804763
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SPRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium, 1070
Public contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com
Scientific contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.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	31 January 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 November 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the dose-response for the efficacy of intravenous (iv) dapirolizumab pegol (DZP; 3 dose groups) at week 24 in adult subjects with moderately to severely active systemic lupus erythematosus (SLE) receiving stable standard-of-care treatment.

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy:

Mandatory background medication with either antimalarials, immunosuppressants or corticosteroids as stand-alone treatment or in combination. Other Background therapy as permitted in the protocol.

Evidence for comparator:

Not Applicable

Actual start date of recruitment	02 June 2016
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	Bulgaria: 2
Country: Number of subjects enrolled	Colombia: 18
Country: Number of subjects enrolled	Germany: 10
Country: Number of subjects enrolled	Mexico: 13
Country: Number of subjects enrolled	Peru: 26
Country: Number of subjects enrolled	Poland: 16
Country: Number of subjects enrolled	Romania: 12
Country: Number of subjects enrolled	Russian Federation: 15
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	Ukraine: 15
Country: Number of subjects enrolled	United States: 53
Worldwide total number of subjects	182
EEA total number of subjects	42

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)	178
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll patients in June 2016 and concluded in November 2018.

Pre-assignment

Screening details:

The study included a 4-week Screening Period, a 24-week Double-Blind Treatment Period and a 24-week Observational Period.
Participant Flow refers to the Randomized Set.

Period 1

Period 1 title	Double-Blind Period (Week 1 to Week 24)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Assessor, Carer, Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	SOC + Placebo iv Q4W

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	PBO
Other name	
Pharmaceutical forms	Solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of PBO every 4 weeks (Q4W) for a total of 6 doses.

Arm title	SOC + DZP 6mg/kg iv Q4W

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6 milligrams (mg)/kilogram (kg) intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Arm type	Experimental
Investigational medicinal product name	Dapirolizumab pegol
Investigational medicinal product code	DZP
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

Arm title	SOC + DZP 24mg/kg iv Q4W

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous

(iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Arm type	Experimental
Investigational medicinal product name	Dapirolizumab pegol
Investigational medicinal product code	DZP
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

Arm title	SOC + DZP 45mg/kg iv Q4W

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Arm type	Experimental
Investigational medicinal product name	Dapirolizumab pegol
Investigational medicinal product code	DZP
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

Number of subjects in period 1	SOC + Placebo iv Q4W	SOC + DZP 6mg/kg iv Q4W	SOC + DZP 24mg/kg iv Q4W
Started	45	45	45
Completed Week 24	44	45	44
Finished Wk24 began Observational Period	44	44	44
Completed	44	44	44
Not completed	1	1	1
Consent withdrawn by subject	-	-	1
Consent withdrawal after Week 24	-	1	-
Adverse event, non-fatal	1	-	-

Number of subjects in period 1	SOC + DZP 45mg/kg iv Q4W
Started	47
Completed Week 24	45
Finished Wk24 began Observational Period	45
Completed	45
Not completed	2
Consent withdrawn by subject	2
Consent withdrawal after Week 24	-
Adverse event, non-fatal	-

Period 2

Period 2 title	Observational Period (Wk 24 to Wk 48)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Assessor, Carer, Investigator, Subject

Blinding implementation details:

Participants who completed the 24-week Double-Blind Treatment Period continued into a 24-week Observational Period, during which participants didn't receive study drug but received standard-of-care (SOC) treatment.
Sponsor was unblinded during the Observational Period.

Arms

Are arms mutually exclusive?	Yes
Arm title	SOC + Placebo iv Q4W

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	PBO
Other name	
Pharmaceutical forms	Solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of PBO every 4 weeks (Q4W) for a total of 6 doses.

Arm title	SOC + DZP 6mg/kg iv Q4W

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6 milligrams (mg)/kilogram (kg) intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Arm type	Experimental
Investigational medicinal product name	Dapirolizumab pegol
Investigational medicinal product code	DZP
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

Arm title	SOC + DZP 24mg/kg iv Q4W

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Arm type	Experimental
Investigational medicinal product name	Dapirolizumab pegol
Investigational medicinal product code	DZP
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

Arm title	SOC + DZP 45mg/kg iv Q4W

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Arm type	Experimental
Investigational medicinal product name	Dapirolizumab pegol
Investigational medicinal product code	DZP
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

Number of subjects in period 2	SOC + Placebo iv Q4W	SOC + DZP 6mg/kg iv Q4W	SOC + DZP 24mg/kg iv Q4W
Started	44	44	44
Completed	38	43	41
Not completed	6	1	3
Consent withdrawn by subject	4	-	2
Patient moved out of state	-	1	-
Lost to follow-up	2	-	1

Number of subjects in period 2	SOC + DZP 45mg/kg iv Q4W
Started	45
Completed	42
Not completed	3
Consent withdrawn by subject	2
Patient moved out of state	-
Lost to follow-up	1

Baseline characteristics

Reporting groups	
Reporting group title	SOC + Placebo iv Q4W
Reporting group description:	
This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.	
Reporting group title	SOC + DZP 6mg/kg iv Q4W
Reporting group description:	
This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6 milligrams (mg)/kilogram (kg) intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.	
Reporting group title	SOC + DZP 24mg/kg iv Q4W
Reporting group description:	
This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.	
Reporting group title	SOC + DZP 45mg/kg iv Q4W
Reporting group description:	
This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.	

Reporting group values	SOC + Placebo iv Q4W	SOC + DZP 6mg/kg iv Q4W	SOC + DZP 24mg/kg iv Q4W
Number of subjects	45	45	45
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	44	44	44
>=65 years	1	1	1
Age continuous Units: years			
arithmetic mean	43.50	40.81	42.77
standard deviation	± 12.79	± 11.55	± 10.42
Gender categorical Units: Subjects			
Male	4	3	5
Female	41	42	40

Reporting group values	SOC + DZP 45mg/kg iv Q4W	Total	
Number of subjects	47	182	
Age categorical Units: Subjects			
<=18 years	0	0	
Between 18 and 65 years	46	178	
>=65 years	1	4	

Age continuous Units: years			
arithmetic mean	38.94		
standard deviation	± 12.92	-	
Gender categorical Units: Subjects			
Male	4	16	
Female	43	166	

End points reporting groups

Reporting group title	SOC + Placebo iv Q4W

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Reporting group title	SOC + DZP 6mg/kg iv Q4W

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6 milligrams (mg)/kilogram (kg) intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Reporting group title	SOC + DZP 24mg/kg iv Q4W

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Reporting group title	SOC + DZP 45mg/kg iv Q4W

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Reporting group title	SOC + Placebo iv Q4W

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Reporting group title	SOC + DZP 6mg/kg iv Q4W

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6 milligrams (mg)/kilogram (kg) intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Reporting group title	SOC + DZP 24mg/kg iv Q4W

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Reporting group title	SOC + DZP 45mg/kg iv Q4W

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Subject analysis set title	SOC + Placebo iv Q4W (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the Full Analysis Set (FAS).

Subject analysis set title	SOC + DZP 6mg/kg iv Q4W (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Participants formed the FAS.

Subject analysis set title	SOC + DZP 24mg/kg iv Q4W (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the FAS.

Subject analysis set title	SOC + DZP 45mg/kg iv Q4W (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the FAS.

Subject analysis set title	SOC + Placebo iv Q4W (SS)
Subject analysis set type	Safety analysis

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the Safety Set (SS).

Subject analysis set title	SOC + DZP 6mg/kg iv Q4W (SS)
Subject analysis set type	Safety analysis

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the SS.

Subject analysis set title	SOC + DZP 24mg/kg iv Q4W (SS)
Subject analysis set type	Safety analysis

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the SS.

Subject analysis set title	SOC + DZP 45mg/kg iv Q4W (SS)
Subject analysis set type	Safety analysis

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the SS.

Primary: Percentage of participants with British Isles Lupus Assessment Group Disease Activity Index 2004 (BILAG 2004)-based Composite Lupus Assessment (BICLA) (mNRI) response across 3 doses of dapirolizumab pegol (DZP) and placebo (PBO) at Week 24

End point title	Percentage of participants with British Isles Lupus Assessment Group Disease Activity Index 2004 (BILAG 2004)-based Composite Lupus Assessment (BICLA) (mNRI) response across 3 doses of dapirolizumab pegol (DZP) and placebo (PBO) at Week 24

End point description:

Primary efficacy variable was assessed by establishing if there was a dose response relationship between BICLA response at Week 24 and dose, using MCP-Mod. 4 candidate dose-response models were evaluated: linear model, logistic model, 2 Emax models, and MCP-Mod methodology controlled for multiplicity.

BICLA response was defined as meeting all of the following criteria: BILAG 2004 improvement: A scores at Baseline improved to B, C or D; B scores improved to C or D; no new A scores and ≤ 1 new B; No

worsening in SLEDAI-2K, defined as no increase in SLEDAI-2K total score; No worsening in PGA, defined as <10 mm increase on a 100 mm VAS; and No disallowed changes in concomitant medications, including increases in corticosteroids, immunosuppressants and antimalarials.

FAS- all participants in Randomized Set with exception of 1 study participant who received less than 1 full dose during study and 5 study participants who were randomized at Site 321. Missing values were imputed using mNRI.

End point type	Primary

End point timeframe:

Week 24

End point values	SOC + Placebo iv Q4W (FAS)	SOC + DZP 6mg/kg iv Q4W (FAS)	SOC + DZP 24mg/kg iv Q4W (FAS)	SOC + DZP 45mg/kg iv Q4W (FAS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	44	46
Units: percentage of participants				
number (not applicable)	0	0	0	0

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Multiple contrast testing (Multiple Comparison Procedure - Modelling (MCP-mod) methodology) was used to test for a statistically significant dose-response relationship between the primary endpoint (BICLA at Week 24) and dose, which would indicate a drug effect of DZP over Placebo.
The best fitting statistically significant model could be used to estimate the dose needed to achieve desired treatment effect.

Comparison groups	SOC + Placebo iv Q4W (FAS) v SOC + DZP 6mg/kg iv Q4W (FAS) v SOC + DZP 24mg/kg iv Q4W (FAS) v SOC + DZP 45mg/kg iv Q4W (FAS)
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0727 [1]
Method	MCP-Mod

Notes:

[1] - The lowest p-value (z-statistic with the highest value) was used to establish proof of dose response.

Secondary: The percentage of participants with BICLA (mNRI) response in the individual dose groups at Week 24

End point title	The percentage of participants with BICLA (mNRI) response in the individual dose groups at Week 24

End point description:

BICLA response was defined as meeting all of the following criteria:
(1)BILAG 2004 improvement: A scores at Baseline improved to B, C or D; B scores improved to C or D; no new A scores and ≤ 1 new B.
(2)No worsening in Systemic Lupus Erythematosus Activity Index 2000 (SLEDAI-2K), defined as no increase in SLEDAI-2K total score.
(3)No worsening in Physician's Global Assessment of Disease Activity (PGA), defined as < 10 millimeter (mm) increase on a 100 mm visual analog scale (VAS).
(4)No disallowed changes in concomitant medications, mainly including increases in corticosteroids,

immunosuppressants, and antimalarials.
The Full Analysis Set (FAS) consisted of all participants in the Randomized Set with the exception of 1 study participant who received less than 1 full dose during the study and 5 study participants who were randomized at Site 321.
Missing values were imputed using a modified non-responder imputation (mNRI).

End point type	Secondary

End point timeframe:

Week 24

End point values	SOC + Placebo iv Q4W (FAS)	SOC + DZP 6mg/kg iv Q4W (FAS)	SOC + DZP 24mg/kg iv Q4W (FAS)	SOC + DZP 45mg/kg iv Q4W (FAS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	43	44	46
Units: percentage of participants				
number (not applicable)	37.2	48.8	54.5	52.2

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

Comparison groups	SOC + Placebo iv Q4W (FAS) v SOC + DZP 6mg/kg iv Q4W (FAS)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2699 [2]
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	3.8

Notes:

[2] - Generalized linear models with factors for treatment and corticosteroid strata were fit using a logit link function for the odds ratios and p-values.

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

Comparison groups	SOC + Placebo iv Q4W (FAS) v SOC + DZP 24mg/kg iv Q4W (FAS)
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1036 [3]
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	4.8

Notes:

[3] - Generalized linear models with factors for treatment and corticosteroid strata were fit using a logit link function for the odds ratios and p-values.

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

Comparison groups	SOC + Placebo iv Q4W (FAS) v SOC + DZP 45mg/kg iv Q4W (FAS)
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1518 [4]
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	4.3

Notes:

[4] - Generalized linear models with factors for treatment and corticosteroid strata were fit using a logit link function for the odds ratios and p-values.

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

Comparison groups	SOC + Placebo iv Q4W (FAS) v SOC + DZP 6mg/kg iv Q4W (FAS)

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
Method	Chi-squared
Parameter estimate	Difference vs PBO
Point estimate	11.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.2
upper limit	32.4

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

Comparison groups	SOC + Placebo iv Q4W (FAS) v SOC + DZP 24mg/kg iv Q4W (FAS)
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
Method	Chi-squared
Parameter estimate	Difference vs PBO
Point estimate	17.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	38

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

Comparison groups	SOC + Placebo iv Q4W (FAS) v SOC + DZP 45mg/kg iv Q4W (FAS)
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
Method	Chi-squared
Parameter estimate	Difference vs PBO
Point estimate	15

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.5
upper limit	35.4

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

Comparison groups	SOC + Placebo iv Q4W (FAS) v SOC + DZP 6mg/kg iv Q4W (FAS)
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
Method	Chi-squared
Parameter estimate	LS Mean Difference vs PBO
Point estimate	11.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.7
upper limit	32.5

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

Comparison groups	SOC + Placebo iv Q4W (FAS) v SOC + DZP 24mg/kg iv Q4W (FAS)
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
Method	Chi-squared
Parameter estimate	LS Mean Difference vs PBO
Point estimate	17.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	38.3

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

Comparison groups	SOC + Placebo iv Q4W (FAS) v SOC + DZP 45mg/kg iv Q4W (FAS)
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
Method	Chi-squared
Parameter estimate	LS Mean Difference vs PBO
Point estimate	15.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.2
upper limit	35.6

Secondary: Percentage of participants with at least one Adverse Events (AEs)

End point title	Percentage of participants with at least one Adverse Events (AEs)

End point description:

An AE was any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product that did not necessarily have a causal relationship with this treatment. An adverse event (AE) was therefore any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. All AEs that occurred during the study were considered related unless clearly unrelated. The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) until end of the study (Week 48)

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: percentage of participants				
number (not applicable)	66.7	66.7	82.2	74.5

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with a Serious Adverse Event (SAE)

End point title	Percentage of participants with a Serious Adverse Event (SAE)

End point description:

A Serious Adverse Event (SAE) must have met 1 or more of the following criteria:
•Death
•Life threatening
•Significant or persistent disability/incapacity
•Congenital anomaly/birth defect (including that occurring in a fetus)
•Important medical event that, based upon appropriate medical judgment, may have jeopardized the study participant, and may have required medical or surgical intervention to prevent 1 of the other outcomes listed in the definition of serious
•Initial inpatient hospitalization or prolongation of hospitalization.
The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) until end of the study (Week 48)

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: percentage of participants				
number (not applicable)	13.3	11.1	13.3	10.6

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with at least one Adverse Events (AEs) of interest

End point title	Percentage of participants with at least one Adverse Events (AEs) of interest

End point description:

Adverse events of interest (AEOI) were identified by the Investigator based on definitions per protocol, documented on the electronic Case Report Form (eCRF), adequately monitored, and source controlled.
AEOI (regardless of seriousness):
•Moderate to severe infections, including opportunistic infections and tuberculosis (TB)
•Infusion reactions (including hypersensitivity and anaphylaxis)
•Thromboembolic events (including but not limited to cardiovascular events, stroke, myocardial

infarction, pulmonary embolism, and deep vein thrombosis)
•Prespecified neurological events: severe and/or serious headache, positional headache, cranial nerve dysfunction, or signs and symptoms of meningitis (photophobia, neck stiffness)
•Malignancies.
The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) until end of the study (Week 48)

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: percentage of participants				
number (not applicable)	24.4	26.7	28.9	25.5

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who permanently withdrew of study drug due to an Adverse Event (AE)

End point title	Percentage of participants who permanently withdrew of study drug due to an Adverse Event (AE)

End point description:

An AE was any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product that did not necessarily have a causal relationship with this treatment. An adverse event (AE) was therefore any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. All AEs that occurred during the study were considered related unless clearly unrelated. The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) until end of the study (Week 48)

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: percentage of participants				
number (not applicable)	8.9	0	4.4	4.3

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Systolic Blood Pressure

End point title	Mean change from baseline in Systolic Blood Pressure

End point description:

Blood pressure was measured in millimetre of mercury (mmHg). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: mmHg				
arithmetic mean (standard deviation)				
Week 2 (45, 45, 45, 44)	3.3 (± 12.9)	5.1 (± 10.5)	0.7 (± 10.7)	3.2 (± 9.9)
Week 4 (43, 44, 43, 46)	0.6 (± 10.8)	1.0 (± 7.9)	-2.0 (± 8.9)	0.6 (± 12.4)
Week 6 (43, 45, 44, 45)	0.3 (± 11.5)	4.0 (± 9.9)	2.3 (± 11.0)	2.4 (± 10.6)
Week 8 (44, 44, 44, 43)	0.5 (± 12.4)	3.3 (± 12.6)	-2.4 (± 9.9)	-0.7 (± 11.9)
Week 12 (44, 45, 45, 44)	-0.7 (± 10.1)	3.2 (± 10.5)	-3.0 (± 11.8)	0.8 (± 9.2)
Week 16 (43, 44, 43, 44)	2.1 (± 12.3)	2.1 (± 11.6)	-2.8 (± 10.6)	0.9 (± 11.1)
Week 20 (42, 45, 42, 44)	1.6 (± 9.9)	2.6 (± 9.8)	-1.7 (± 12.3)	1.5 (± 11.3)
Week 24 (43, 44, 44, 44)	-0.7 (± 14.3)	1.1 (± 13.1)	0.3 (± 11.0)	3.6 (± 9.3)
Week 28 (44, 43, 42, 44)	1.8 (± 12.3)	3.7 (± 13.1)	0.9 (± 10.5)	2.5 (± 11.8)
Week 32 (44, 44, 43, 45)	2.2 (± 11.1)	3.0 (± 13.2)	0.4 (± 11.3)	4.3 (± 13.7)
Week 36 (42, 42, 41, 41)	2.1 (± 11.0)	3.1 (± 12.6)	0.2 (± 10.5)	2.4 (± 12.9)
Week 40 (42, 43, 41, 44)	-1.0 (± 14.1)	6.2 (± 12.9)	-2.0 (± 11.7)	2.5 (± 11.3)
Week 44 (39, 41, 41, 42)	0.1 (± 12.6)	3.3 (± 14.1)	1.3 (± 10.4)	4.2 (± 11.8)
Week 48 (38, 42, 40, 42)	-1.5 (± 11.5)	4.9 (± 14.3)	0.1 (± 10.2)	4.4 (± 12.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Diastolic Blood Pressure

End point title	Mean change from baseline in Diastolic Blood Pressure

End point description:

Blood pressure was measured in millimetre of mercury (mmHg). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: mmHg				
arithmetic mean (standard deviation)				
Week 2 (45, 45, 45, 44)	2.1 (± 10.5)	1.4 (± 8.6)	1.5 (± 9.3)	2.4 (± 8.2)
Week 4 (43, 44, 43, 46)	-0.7 (± 7.8)	-1.5 (± 6.3)	-1.7 (± 8.2)	-0.1 (± 8.3)
Week 6 (43, 45, 44, 45)	1.0 (± 10.0)	1.5 (± 8.6)	1.8 (± 10.0)	1.9 (± 7.9)
Week 8 (44, 44, 44, 43)	1.1 (± 9.2)	0.4 (± 9.1)	0.1 (± 8.6)	1.0 (± 8.0)
Week 12 (44, 45, 45, 44)	-0.9 (± 8.4)	-0.3 (± 6.9)	-2.2 (± 9.6)	-0.3 (± 6.9)
Week 16 (43, 44, 43, 44)	-0.3 (± 8.9)	-1.3 (± 7.6)	-0.7 (± 9.5)	-0.1 (± 7.0)
Week 20 (42, 45, 42, 44)	1.5 (± 8.1)	-1.1 (± 8.7)	-0.7 (± 9.6)	0.9 (± 8.8)
Week 24 (43, 44, 44, 44)	1.9 (± 11.2)	1.6 (± 8.7)	2.3 (± 10.7)	0.6 (± 8.7)
Week 28 (44, 43, 42, 44)	1.5 (± 9.1)	-0.2 (± 8.8)	1.4 (± 8.4)	2.5 (± 8.4)
Week 32 (44, 44, 43, 45)	2.3 (± 10.1)	2.8 (± 9.3)	0.7 (± 10.2)	2.3 (± 8.1)
Week 36 (42, 42, 41, 41)	3.4 (± 9.8)	1.4 (± 10.2)	1.4 (± 8.4)	2.2 (± 8.0)
Week 40 (42, 43, 41, 44)	1.0 (± 9.2)	2.6 (± 7.6)	0.5 (± 9.9)	3.6 (± 8.8)
Week 44 (39, 41, 41, 42)	0.8 (± 10.2)	1.5 (± 8.1)	0.4 (± 9.4)	2.2 (± 10.3)
Week 48 (38, 42, 40, 42)	1.4 (± 9.0)	2.3 (± 8.8)	1.1 (± 9.4)	2.4 (± 8.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Pulse Rate

End point title	Mean change from baseline in Pulse Rate

End point description:

Pulse Rate was measured in beats per minute (beats/min). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: beats/min				
arithmetic mean (standard deviation)				
Week 2 (45, 45, 45, 44)	-0.2 (± 8.3)	0.2 (± 10.4)	2.3 (± 9.7)	-0.9 (± 10.4)
Week 4 (43, 44, 43, 46)	1.7 (± 9.6)	1.5 (± 8.0)	0.4 (± 8.4)	-3.3 (± 9.7)
Week 6 (43, 45, 44, 45)	-0.7 (± 10.2)	0.1 (± 8.5)	0.8 (± 8.9)	-0.6 (± 8.8)
Week 8 (44, 44, 44, 43)	1.3 (± 9.0)	0.3 (± 9.2)	1.4 (± 10.2)	-2.6 (± 10.2)
Week 12 (44, 45, 45, 44)	0.6 (± 10.3)	1.1 (± 9.8)	-0.3 (± 10.4)	-1.5 (± 9.7)
Week 16 (43, 44, 43, 44)	-0.8 (± 9.2)	0.3 (± 8.9)	0.9 (± 10.7)	-1.6 (± 10.6)
Week 20 (42, 45, 42, 44)	0.3 (± 10.6)	1.1 (± 9.9)	0.8 (± 9.5)	0.4 (± 6.6)
Week 24 (43, 44, 44, 44)	-1.5 (± 10.7)	0.8 (± 10.9)	-0.3 (± 10.2)	-1.0 (± 8.7)
Week 28 (44, 43, 42, 44)	0.6 (± 11.8)	1.3 (± 10.9)	0.0 (± 9.2)	0.6 (± 8.8)
Week 32 (44, 44, 43, 45)	0.4 (± 9.8)	1.3 (± 10.9)	0.8 (± 11.4)	-2.1 (± 11.0)
Week 36 (42, 42, 41, 41)	-0.7 (± 10.9)	0.2 (± 8.3)	0.7 (± 10.4)	-0.2 (± 9.8)
Week 40 (42, 43, 41, 44)	-0.1 (± 10.9)	-0.1 (± 9.8)	0.6 (± 10.2)	-1.3 (± 9.6)
Week 44 (39, 41, 41, 42)	-0.2 (± 10.2)	-0.1 (± 9.8)	0.3 (± 11.7)	-0.6 (± 8.9)
Week 48 (38, 42, 40, 42)	-0.2 (± 11.1)	-0.7 (± 10.6)	-0.9 (± 11.9)	-2.0 (± 7.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Temperature

End point title	Mean change from baseline in Temperature

End point description:

Temperature was measured in Grad Celsius (°C). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: Temperature (C)				
arithmetic mean (standard deviation)				
Week 2 (45, 45, 45, 44)	-0.1 (± 0.4)	0.0 (± 0.3)	0.1 (± 0.5)	0.0 (± 0.4)
Week 4 (43, 44, 43, 46)	-0.1 (± 0.4)	0.0 (± 0.4)	0.0 (± 0.4)	0.0 (± 0.3)
Week 6 (43, 45, 44, 45)	-0.2 (± 0.5)	0.0 (± 0.4)	0.1 (± 0.5)	0.0 (± 0.5)
Week 8 (44, 44, 44, 43)	-0.1 (± 0.4)	-0.1 (± 0.3)	0.0 (± 0.4)	0.0 (± 0.4)
Week 12 (44, 45, 45, 44)	-0.1 (± 0.4)	-0.1 (± 0.4)	0.0 (± 0.3)	0.0 (± 0.4)

Week 16 (43, 44, 43, 44)	-0.1 (± 0.4)	0.0 (± 0.4)	0.0 (± 0.4)	0.0 (± 0.3)
Week 20 (42, 45, 42, 44)	-0.1 (± 0.4)	0.0 (± 0.4)	0.0 (± 0.4)	0.0 (± 0.5)
Week 24 (43, 44, 44, 44)	-0.1 (± 0.5)	0.0 (± 0.4)	0.1 (± 0.5)	0.0 (± 0.4)
Week 28 (44, 43,42 , 44)	0.0 (± 0.4)	0.0 (± 0.4)	0.1 (± 0.5)	0.1 (± 0.5)
Week 32 (44, 44, 43, 45)	0.0 (± 0.4)	0.0 (± 0.4)	0.1 (± 0.5)	0.0 (± 0.4)
Week 36 (42, 42, 41, 41)	-0.1 (± 0.3)	0.0 (± 0.6)	0.0 (± 0.4)	0.1 (± 0.4)
Week 40 (42, 43, 41, 44)	0.0 (± 0.4)	0.0 (± 0.4)	0.0 (± 0.5)	0.1 (± 0.3)
Week 44 (39, 41, 41, 42)	0.0 (± 0.6)	0.0 (± 0.5)	0.1 (± 0.4)	0.0 (± 0.4)
Week 48 (38, 42, 40, 42)	-0.1 (± 0.4)	0.0 (± 0.4)	0.0 (± 0.5)	0.0 (± 0.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Weight

End point title	Mean change from baseline in Weight

End point description:

Weight was measured in kilograms (kg). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 1), Week 4, Week 8, Week 12, Week 16, and Week 20

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: kg				
arithmetic mean (standard deviation)				
Week 4 (43, 44, 43, 46)	0.0 (± 1.0)	0.2 (± 1.0)	0.4 (± 0.9)	0.3 (± 1.2)
Week 8 (44, 44, 43, 43)	0.3 (± 1.9)	0.6 (± 1.4)	0.6 (± 1.8)	0.4 (± 1.8)
Week 12 (43, 45, 44, 44)	0.4 (± 2.3)	0.5 (± 1.6)	0.5 (± 2.0)	0.6 (± 2.3)
Week 16 (43, 44, 43, 44)	0.3 (± 2.3)	0.7 (± 2.3)	0.8 (± 2.3)	0.5 (± 2.4)
Week 20 (42, 45, 42, 44)	0.3 (± 2.4)	0.7 (± 2.6)	1.0 (± 2.6)	0.5 (± 2.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Height

End point title	Mean change from baseline in Height

End point description:

Height was measured in centimeters (cm). The Safety Set (SS) consisted of all study participants who

were randomized and received at least 1 dose (any amount) of study drug. Here, '999' was used as a placeholder and signifies that height was only measured at Screening as per planned analysis. Therefore, data was not collected for this outcome measure.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: cm				
arithmetic mean (standard deviation)	999 (± 999)	999 (± 999)	999 (± 999)	999 (± 999)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with 12-Lead electrocardiogram (ECG) abnormal findings

End point title	Number of participants with 12-Lead electrocardiogram (ECG) abnormal findings

End point description:

Twelve-lead ECG assessments should have been performed prior to dosing (if applicable) and prior to obtaining pharmacokinetic (PK) or other laboratory samples. Electrocardiograms were recorded digitally and read by the Investigator for recording in the electronic Case Report Form (eCRF). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug.

End point type	Secondary

End point timeframe:

Screening, Week 4, Week 24, Week 28, and Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: participants				
Screening	8	11	6	6
Week 4	11	12	7	10
Week 24	9	7	6	10
Week 28	1	0	0	0
Week 48	8	7	11	9

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Hemoglobin

End point title	Mean change from baseline in Hemoglobin

End point description:

Hemoglobin was measured in grams per liter (g/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: g/L				
arithmetic mean (standard deviation)				
Week 2 (44, 42, 45, 42)	0.4 (± 6.4)	-1.8 (± 5.8)	-0.7 (± 6.9)	-0.7 (± 6.8)
Week 4 (44, 44, 43, 46)	-1.0 (± 7.2)	-0.7 (± 7.7)	-1.4 (± 8.6)	-0.8 (± 5.8)
Week 8 (43, 44, 44, 44)	-0.3 (± 7.3)	-1.9 (± 7.9)	-1.9 (± 8.6)	-1.3 (± 7.4)
Week 12 (44, 44, 44, 44)	-0.5 (± 9.5)	-0.5 (± 8.5)	-0.5 (± 10.1)	0.2 (± 8.3)
Week 16 (44, 43, 43, 45)	0.3 (± 10.4)	-0.3 (± 10.0)	-0.8 (± 10.6)	-2.7 (± 8.3)
Week 20 (43, 43, 41, 43)	-0.7 (± 11.5)	0.3 (± 9.9)	-0.5 (± 10.1)	-2.4 (± 7.2)
Week 24 (42, 43, 44, 44)	-0.4 (± 9.7)	-0.7 (± 11.2)	-0.7 (± 10.5)	-2.9 (± 8.1)
Week 28 (44, 41, 41, 44)	0.7 (± 10.6)	-3.4 (± 11.0)	0.0 (± 14.1)	-3.1 (± 9.5)
Week 32 (43, 43, 43, 42)	1.6 (± 12.5)	-1.3 (± 9.8)	1.0 (± 12.5)	-1.3 (± 9.6)
Week 40 (42, 43, 41, 44)	0.7 (± 13.5)	-0.3 (± 13.5)	1.9 (± 14.9)	1.1 (± 11.0)
Week 48 (38, 42, 39, 42)	-0.5 (± 14.3)	-1.5 (± 11.6)	0.9 (± 12.5)	-0.7 (± 10.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Hematocrit

End point title	Mean change from baseline in Hematocrit

End point description:

Hematocrit was measured in volume percentage (%) of red blood cells in blood. The Safety Set (SS)

consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: volume % of red blood cells				
arithmetic mean (standard deviation)				
Week 2 (44, 42, 45, 42)	0.42 (± 2.52)	-0.25 (± 2.26)	-0.32 (± 2.37)	0.00 (± 2.71)
Week 4 (44, 44, 43, 46)	-0.46 (± 2.29)	-0.17 (± 2.75)	-0.79 (± 2.92)	-0.11 (± 2.31)
Week 8 (43, 44, 44, 44)	-0.27 (± 2.23)	-0.12 (± 2.94)	-0.86 (± 2.72)	-0.42 (± 2.31)
Week 12 (44, 44, 44, 44)	-0.23 (± 2.67)	-0.13 (± 2.72)	-0.32 (± 3.39)	-0.02 (± 2.54)
Week 16 (44, 43, 43, 45)	-0.12 (± 2.86)	0.05 (± 3.25)	-0.57 (± 3.32)	-0.84 (± 2.95)
Week 20 (43, 43, 41, 43)	-0.41 (± 3.20)	0.13 (± 2.99)	-0.42 (± 3.32)	-0.80 (± 2.83)
Week 24 (42, 43, 44, 44)	-0.09 (± 2.61)	-0.40 (± 3.19)	-0.29 (± 3.14)	-0.76 (± 2.33)
Week 28 (44, 41, 41, 44)	0.03 (± 2.98)	-1.02 (± 3.23)	-0.22 (± 3.99)	-0.89 (± 2.47)
Week 32 (43, 43, 43, 42)	0.29 (± 2.89)	-0.62 (± 2.86)	0.17 (± 3.43)	-0.21 (± 2.82)
Week 40 (42, 43, 41, 44)	-0.20 (± 3.32)	-0.24 (± 4.37)	0.58 (± 4.11)	0.37 (± 2.72)
Week 48 (38, 42, 39, 42)	-0.59 (± 3.51)	-0.37 (± 3.58)	-0.08 (± 3.21)	-0.11 (± 2.54)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Erythrocytes

End point title	Mean change from baseline in Erythrocytes

End point description:

Erythrocytes was measured in number of erythrocytes per liter (10^12/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: 10^12 erythrocytes per liter				
arithmetic mean (standard deviation)				
Week 2 (44, 42, 45, 42)	-0.004 (± 0.246)	-0.035 (± 0.237)	-0.032 (± 0.223)	-0.028 (± 0.237)
Week 4 (44, 44, 43, 46)	-0.080 (± 0.243)	-0.018 (± 0.293)	-0.052 (± 0.273)	-0.033 (± 0.210)
Week 8 (43, 44, 44, 44)	-0.039 (± 0.224)	-0.039 (± 0.280)	-0.069 (± 0.262)	-0.044 (± 0.242)
Week 12 (44, 44, 44, 44)	-0.024 (± 0.271)	0.014 (± 0.292)	-0.010 (± 0.267)	0.019 (± 0.226)
Week 16 (44, 43, 43, 45)	-0.002 (± 0.312)	0.041 (± 0.360)	0.000 (± 0.302)	-0.051 (± 0.265)
Week 20 (43, 43, 41, 43)	-0.029 (± 0.333)	0.062 (± 0.309)	-0.001 (± 0.325)	-0.047 (± 0.302)
Week 24 (42, 43, 44, 44)	0.005 (± 0.308)	0.036 (± 0.312)	0.013 (± 0.319)	-0.038 (± 0.240)
Week 28 (44, 41, 41, 44)	0.018 (± 0.340)	-0.040 (± 0.304)	0.019 (± 0.346)	-0.050 (± 0.270)
Week 32 (43, 43, 43, 42)	0.048 (± 0.320)	0.001 (± 0.284)	0.032 (± 0.289)	0.027 (± 0.277)
Week 40 (42, 43, 41, 44)	-0.005 (± 0.343)	0.042 (± 0.382)	0.054 (± 0.368)	0.060 (± 0.256)
Week 48 (38, 42, 39, 42)	-0.024 (± 0.332)	-0.018 (± 0.295)	0.017 (± 0.299)	-0.028 (± 0.245)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Erythrocytes Mean Corpuscular Volume

End point title	Mean change from baseline in Erythrocytes Mean Corpuscular Volume

End point description:

Erythrocytes Mean Corpuscular Volume was measured in femtolitres (fL). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: Femtolitres (fL)				
arithmetic mean (standard deviation)				

Week 2 (44, 42, 45, 42)	1.01 (± 2.28)	0.24 (± 2.40)	-0.09 (± 2.66)	0.45 (± 2.96)
Week 4 (44, 44, 43, 46)	0.60 (± 2.35)	0.08 (± 2.66)	-0.68 (± 2.10)	0.40 (± 3.02)
Week 8 (43, 44, 44, 44)	0.23 (± 3.48)	-0.30 (± 5.36)	-0.54 (± 2.85)	-0.16 (± 2.79)
Week 12 (44, 44, 44, 44)	0.06 (± 3.57)	-0.52 (± 3.44)	-0.55 (± 4.67)	-0.57 (± 3.09)
Week 16 (44, 43, 43, 45)	-0.25 (± 3.41)	-0.65 (± 4.38)	-1.38 (± 4.87)	-0.97 (± 3.62)
Week 20 (43, 43, 41, 43)	-0.37 (± 3.73)	-0.92 (± 4.58)	-1.00 (± 5.01)	-0.97 (± 3.54)
Week 24 (42, 43, 44, 44)	-0.23 (± 3.83)	-1.63 (± 4.07)	-0.92 (± 6.51)	-1.05 (± 4.00)
Week 28 (44, 41, 41,44)	-0.33 (± 3.61)	-1.40 (± 4.61)	-0.96 (± 6.46)	-1.21 (± 4.91)
Week 32 (43, 43, 43, 42)	-0.27 (± 4.45)	-1.33 (± 4.32)	-0.45 (± 6.81)	-1.06 (± 4.69)
Week 40 (42, 43, 41, 44)	-0.36 (± 5.34)	-1.46 (± 4.72)	0.07 (± 6.27)	-0.24 (± 4.85)
Week 48 (38, 42, 39, 42)	-0.98 (± 5.34)	-0.50 (± 4.97)	-0.63 (± 6.92)	0.34 (± 4.31)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Erythrocytes Mean Corpuscular Hemoglobin (HGB) Concentration

End point title	Mean change from baseline in Erythrocytes Mean Corpuscular Hemoglobin (HGB) Concentration

End point description:

Erythrocytes Mean Corpuscular Hemoglobin (HGB) Concentration was measured in grams per liter (g/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: g/L				
arithmetic mean (standard deviation)				
Week 2 (44, 42, 45, 42)	-2.3 (± 9.8)	-2.6 (± 10.9)	0.7 (± 9.8)	-1.9 (± 10.1)
Week 4 (44, 44, 43, 46)	1.4 (± 8.7)	-0.9 (± 10.1)	2.7 (± 8.6)	-1.2 (± 12.5)
Week 8 (43, 44, 44, 44)	1.7 (± 11.5)	-3.8 (± 13.4)	2.1 (± 8.2)	-0.1 (± 11.5)
Week 12 (44, 44, 44, 44)	0.5 (± 11.1)	-0.6 (± 10.7)	0.6 (± 12.3)	0.5 (± 12.7)
Week 16 (44, 43, 43, 45)	1.6 (± 13.8)	-1.5 (± 10.1)	2.3 (± 11.3)	-0.2 (± 14.1)
Week 20 (43, 43, 41, 43)	1.6 (± 12.9)	-0.9 (± 11.3)	2.4 (± 11.2)	0.4 (± 12.6)
Week 24 (42, 43, 44, 44)	0.0 (± 13.7)	1.0 (± 13.2)	0.4 (± 12.8)	-1.2 (± 13.1)
Week 28 (44, 41, 41, 44)	1.6 (± 13.4)	-1.3 (± 14.4)	1.7 (± 13.8)	-0.6 (± 16.5)
Week 32 (43, 43, 43, 42)	1.7 (± 18.9)	1.1 (± 13.8)	1.2 (± 15.0)	-1.4 (± 16.0)
Week 40 (42, 43, 41, 44)	3.4 (± 17.6)	0.8 (± 16.5)	0.1 (± 15.8)	0.1 (± 15.4)
Week 48 (38, 42, 39, 42)	3.6 (± 17.1)	-0.6 (± 16.2)	2.9 (± 14.5)	0.0 (± 13.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Erythrocytes Mean Corpuscular Hemoglobin

End point title	Mean change from baseline in Erythrocytes Mean Corpuscular Hemoglobin

End point description:

Erythrocytes Mean Corpuscular Hemoglobin was measured in picograms (pg). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: Picograms (pg)				
arithmetic mean (standard deviation)				
Week 2 (44, 42, 45, 42)	0.12 (± 0.71)	-0.18 (± 0.65)	0.04 (± 0.43)	0.00 (± 0.47)
Week 4 (44, 44, 43, 46)	0.31 (± 0.63)	-0.06 (± 0.79)	0.04 (± 0.64)	0.02 (± 0.65)
Week 8 (43, 44, 44, 44)	0.20 (± 0.87)	-0.25 (± 0.87)	0.04 (± 0.81)	-0.04 (± 0.74)
Week 12 (44, 44, 44, 44)	0.04 (± 1.08)	-0.25 (± 1.03)	-0.09 (± 1.25)	-0.12 (± 0.90)
Week 16 (44, 43, 43, 45)	0.03 (± 1.43)	-0.36 (± 1.31)	-0.20 (± 1.52)	-0.31 (± 1.19)
Week 20 (43, 43, 41, 43)	0.00 (± 1.49)	-0.39 (± 1.40)	-0.10 (± 1.63)	-0.26 (± 1.24)
Week 24 (42, 43, 44, 44)	-0.13 (± 1.57)	-0.43 (± 1.39)	-0.25 (± 1.96)	-0.44 (± 1.42)
Week 28 (44, 41, 41, 44)	0.01 (± 1.68)	-0.55 (± 1.45)	-0.15 (± 2.09)	-0.44 (± 1.68)
Week 32 (43, 43, 43, 42)	0.01 (± 2.12)	-0.33 (± 1.28)	-0.06 (± 2.39)	-0.48 (± 1.63)
Week 40 (42, 43, 41, 44)	0.17 (± 2.50)	-0.40 (± 1.30)	0.03 (± 2.32)	-0.09 (± 2.00)
Week 48 (38, 42, 39, 42)	0.02 (± 2.58)	-0.21 (± 1.48)	0.06 (± 2.55)	0.10 (± 1.90)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Leukocytes

End point title	Mean change from baseline in Leukocytes

End point description:

Leukocytes was measured in number of leukocytes per liter (10^9/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: 10^9 leukocytes per liter				
arithmetic mean (standard deviation)				
Week 2 (44, 42, 45, 42)	0.34 (± 2.45)	0.27 (± 1.23)	0.49 (± 1.46)	0.20 (± 1.62)
Week 4 (44, 44, 43, 46)	0.10 (± 1.88)	0.27 (± 1.63)	0.25 (± 1.47)	0.52 (± 2.11)
Week 8 (43, 44, 44, 44)	-0.25 (± 2.12)	0.46 (± 1.41)	-0.05 (± 1.50)	-0.10 (± 1.65)
Week 12 (44, 44, 44, 43)	-0.27 (± 1.80)	0.18 (± 1.73)	0.17 (± 2.00)	0.23 (± 2.01)
Week 16 (44, 43, 43, 45)	-0.31 (± 2.18)	0.13 (± 1.55)	0.21 (± 1.69)	-0.20 (± 2.12)
Week 20 (43, 43, 41, 43)	-0.24 (± 2.27)	-0.06 (± 1.59)	-0.22 (± 1.74)	0.30 (± 2.61)
Week 24 (42, 43, 44, 44)	-0.22 (± 2.41)	-0.12 (± 1.83)	-0.14 (± 1.75)	-0.34 (± 1.97)
Week 28 (44, 41, 41, 44)	0.05 (± 2.04)	0.06 (± 1.93)	0.26 (± 2.04)	-0.58 (± 1.70)
Week 32 (43, 43, 43, 42)	-0.14 (± 2.20)	0.08 (± 1.64)	0.19 (± 1.67)	-0.44 (± 1.68)
Week 40 (42, 43, 41, 44)	0.17 (± 2.54)	0.04 (± 1.60)	-0.35 (± 1.49)	-0.49 (± 1.96)
Week 48 (38, 42, 39, 42)	-0.49 (± 1.83)	0.30 (± 1.53)	-0.14 (± 2.06)	-0.62 (± 1.87)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Basophils

End point title	Mean change from baseline in Basophils

End point description:

Basophils was measured in number of basophils per liter (10^9/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: 10^9 basophils per liter				
arithmetic mean (standard deviation)				
Week 2 (42, 39, 44, 41)	0.01 (± 0.03)	0.02 (± 0.04)	0.00 (± 0.03)	0.00 (± 0.02)
Week 4 (43, 43, 41, 46)	0.01 (± 0.03)	0.00 (± 0.03)	0.01 (± 0.04)	0.00 (± 0.02)
Week 8 (42, 41, 43, 43)	0.01 (± 0.04)	0.01 (± 0.04)	0.01 (± 0.03)	0.00 (± 0.02)
Week 12 (44, 40, 44, 42)	0.01 (± 0.03)	0.01 (± 0.04)	0.00 (± 0.03)	0.00 (± 0.03)
Week 16 (43, 42, 43, 44)	0.01 (± 0.04)	0.00 (± 0.03)	0.01 (± 0.03)	0.00 (± 0.03)
Week 20 (42, 40, 40, 42)	0.00 (± 0.03)	0.01 (± 0.03)	0.00 (± 0.03)	0.00 (± 0.03)
Week 24 (41, 40, 44, 44)	0.00 (± 0.03)	0.02 (± 0.04)	0.00 (± 0.03)	0.00 (± 0.03)
Week 28 (44, 39, 40, 44)	0.02 (± 0.05)	0.01 (± 0.04)	0.00 (± 0.02)	0.00 (± 0.03)
Week 32 (41, 40, 43, 42)	0.00 (± 0.03)	0.00 (± 0.02)	0.01 (± 0.03)	0.00 (± 0.03)
Week 40 (41, 42, 40, 43)	0.00 (± 0.02)	0.00 (± 0.02)	0.01 (± 0.03)	0.00 (± 0.03)
Week 48 (37, 41, 39, 41)	0.00 (± 0.03)	0.00 (± 0.02)	0.00 (± 0.03)	0.01 (± 0.03)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Basophils/Leukocytes

End point title	Mean change from baseline in Basophils/Leukocytes

End point description:

Basophils/Leukocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: % of Basophils per Leukocytes				
arithmetic mean (standard deviation)				
Week 2 (42, 39, 44, 41)	-0.05 (± 0.23)	0.02 (± 0.20)	-0.05 (± 0.31)	-0.03 (± 0.27)
Week 4 (43, 43, 41, 46)	0.03 (± 0.27)	-0.06 (± 0.26)	-0.01 (± 0.43)	-0.07 (± 0.26)
Week 8 (42, 41, 43, 43)	0.08 (± 0.42)	0.03 (± 0.32)	0.00 (± 0.33)	-0.06 (± 0.23)
Week 12 (44, 40, 44, 42)	0.04 (± 0.30)	0.09 (± 0.48)	0.00 (± 0.25)	-0.07 (± 0.28)
Week 16 (43, 42, 43, 44)	0.01 (± 0.25)	0.00 (± 0.28)	-0.02 (± 0.31)	-0.05 (± 0.30)
Week 20 (42, 40, 40, 42)	-0.02 (± 0.26)	0.00 (± 0.27)	-0.07 (± 0.29)	-0.04 (± 0.32)
Week 24 (41, 40, 44, 44)	-0.04 (± 0.31)	0.15 (± 0.44)	-0.03 (± 0.24)	-0.03 (± 0.21)
Week 28 (44, 39, 40, 44)	0.08 (± 0.54)	0.03 (± 0.29)	0.00 (± 0.24)	0.07 (± 0.32)

Week 32 (41, 40, 43, 42)	-0.03 (± 0.29)	0.00 (± 0.23)	0.01 (± 0.25)	0.01 (± 0.25)
Week 40 (41, 42, 40, 43)	-0.08 (± 0.24)	-0.03 (± 0.25)	0.07 (± 0.29)	0.01 (± 0.29)
Week 48 (37, 41, 39, 41)	-0.01 (± 0.29)	-0.08 (± 0.21)	0.02 (± 0.25)	0.06 (± 0.28)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Eosinophils

End point title	Mean change from baseline in Eosinophils

End point description:

Eosinophils was measured in number of eosinophils per liter (10^9/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: 10^9 eosinophils per liter				
arithmetic mean (standard deviation)				
Week 2 (42, 39, 44, 41)	-0.01 (± 0.04)	0.01 (± 0.06)	0.00 (± 0.09)	-0.01 (± 0.05)
Week 4 (43, 43, 41, 46)	-0.01 (± 0.04)	-0.01 (± 0.06)	0.00 (± 0.04)	-0.01 (± 0.04)
Week 8 (42, 41, 43, 43)	-0.01 (± 0.04)	0.03 (± 0.16)	0.00 (± 0.04)	0.01 (± 0.07)
Week 12 (44, 40, 44, 42)	0.00 (± 0.04)	0.04 (± 0.20)	0.02 (± 0.10)	0.02 (± 0.17)
Week 16 (43, 42, 43, 44)	0.00 (± 0.05)	0.02 (± 0.11)	0.01 (± 0.05)	0.00 (± 0.06)
Week 20 (42, 40, 40, 42)	0.00 (± 0.05)	0.04 (± 0.24)	0.01 (± 0.05)	-0.01 (± 0.05)
Week 24 (41, 40, 44, 44)	-0.01 (± 0.05)	0.04 (± 0.15)	0.02 (± 0.07)	-0.02 (± 0.06)
Week 28 (44, 39, 40, 44)	-0.01 (± 0.04)	0.01 (± 0.07)	0.01 (± 0.05)	0.00 (± 0.06)
Week 32 (41, 40, 43, 42)	-0.01 (± 0.06)	0.01 (± 0.10)	0.01 (± 0.05)	-0.02 (± 0.04)
Week 40 (41, 42, 40, 43)	0.00 (± 0.05)	0.01 (± 0.06)	0.02 (± 0.06)	0.00 (± 0.07)
Week 48 (37, 41, 39, 41)	0.00 (± 0.04)	-0.01 (± 0.05)	0.00 (± 0.06)	0.00 (± 0.06)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Eosinophils/Leukocytes

End point title	Mean change from baseline in Eosinophils/Leukocytes

End point description:

Eosinophils/Leukocytes was measured in percentages (%). The Safety Set (SS) consisted of all study

participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: % of Eosinophils per Leukocytes				
arithmetic mean (standard deviation)				
Week 2 (42, 39, 44, 41)	-0.19 (± 1.07)	0.07 (± 0.86)	-0.18 (± 1.13)	-0.29 (± 1.22)
Week 4 (43, 43, 41, 46)	-0.32 (± 0.96)	-0.05 (± 1.26)	-0.12 (± 1.01)	-0.26 (± 0.94)
Week 8 (42, 41, 43, 43)	-0.05 (± 1.09)	0.54 (± 2.13)	0.10 (± 1.11)	0.22 (± 1.89)
Week 12 (44, 40, 44, 42)	0.18 (± 1.03)	0.70 (± 3.12)	0.33 (± 1.68)	0.05 (± 1.83)
Week 16 (43, 42, 43, 44)	0.06 (± 1.05)	0.36 (± 1.24)	0.20 (± 1.40)	-0.11 (± 1.33)
Week 20 (42, 40, 40, 42)	0.04 (± 1.11)	0.83 (± 3.58)	0.11 (± 1.24)	-0.39 (± 1.29)
Week 24 (41, 40, 44, 44)	0.11 (± 1.16)	0.82 (± 2.89)	-0.01 (± 1.22)	0.06 (± 1.63)
Week 28 (44, 39, 40, 44)	0.06 (± 1.00)	0.21 (± 1.33)	0.18 (± 1.02)	-0.03 (± 1.35)
Week 32 (41, 40, 43, 42)	0.02 (± 1.09)	0.28 (± 1.60)	0.16 (± 1.13)	-0.20 (± 1.03)
Week 40 (41, 42, 40, 43)	-0.10 (± 0.85)	0.05 (± 1.09)	0.40 (± 1.23)	-0.09 (± 1.47)
Week 48 (37, 41, 39, 41)	0.09 (± 1.02)	-0.17 (± 1.08)	0.06 (± 0.90)	0.24 (± 1.03)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Lymphocytes

End point title	Mean change from baseline in Lymphocytes

End point description:

Lymphocytes was measured in number of lymphocytes per liter (10^9/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: 10^9 lymphocytes per liter				
arithmetic mean (standard deviation)				
Week 2 (42, 39, 44, 41)	-0.03 (± 0.39)	0.05 (± 0.36)	0.16 (± 0.29)	0.24 (± 0.37)
Week 4 (43, 43, 41, 46)	-0.04 (± 0.36)	-0.01 (± 0.47)	-0.01 (± 0.41)	0.23 (± 0.42)
Week 8 (42, 41, 43, 43)	-0.15 (± 0.48)	-0.03 (± 0.39)	0.06 (± 0.46)	0.14 (± 0.50)
Week 12 (44, 40, 44, 42)	-0.06 (± 0.43)	0.02 (± 0.59)	0.01 (± 0.42)	0.21 (± 0.51)
Week 16 (43, 42, 43, 44)	-0.09 (± 0.52)	-0.11 (± 0.51)	-0.02 (± 0.47)	0.04 (± 0.40)
Week 20 (42, 40, 40, 42)	-0.14 (± 0.56)	-0.13 (± 0.54)	0.02 (± 0.39)	0.13 (± 0.55)
Week 24 (41, 40, 44, 44)	-0.11 (± 0.51)	-0.08 (± 0.60)	-0.03 (± 0.45)	0.05 (± 0.52)
Week 28 (44, 39, 40, 44)	-0.04 (± 0.57)	-0.02 (± 0.59)	0.01 (± 0.53)	0.03 (± 0.56)
Week 32 (41, 40, 43, 42)	-0.11 (± 0.57)	-0.16 (± 0.59)	0.05 (± 0.45)	-0.02 (± 0.44)
Week 40 (41, 42, 40, 43)	-0.11 (± 0.54)	-0.11 (± 0.52)	-0.11 (± 0.43)	-0.03 (± 0.48)
Week 48 (37, 41, 39, 41)	-0.19 (± 0.68)	-0.19 (± 0.60)	-0.10 (± 0.44)	-0.02 (± 0.49)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Lymphocytes/Leukocytes

End point title	Mean change from baseline in Lymphocytes/Leukocytes

End point description:

Lymphocytes/Leukocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: % of Lymphocytes per Leukocytes				
arithmetic mean (standard deviation)				
Week 2 (42, 39, 44, 41)	-1.88 (± 9.01)	0.19 (± 6.55)	1.18 (± 6.09)	2.61 (± 6.11)
Week 4 (43, 43, 41, 46)	-0.88 (± 7.09)	-1.02 (± 6.34)	-1.18 (± 9.93)	0.97 (± 8.00)
Week 8 (42, 41, 43, 43)	-1.98 (± 10.59)	-1.40 (± 7.13)	0.56 (± 10.20)	1.97 (± 8.51)
Week 12 (44, 40, 44, 42)	0.21 (± 7.87)	0.56 (± 10.58)	-0.44 (± 9.90)	2.46 (± 10.18)
Week 16 (43, 42, 43, 44)	-0.91 (± 8.33)	-1.49 (± 7.50)	-1.18 (± 9.65)	0.12 (± 9.34)
Week 20 (42, 40, 40, 42)	-1.97 (± 10.37)	-0.66 (± 6.58)	0.88 (± 10.69)	0.71 (± 10.32)

Week 24 (41, 40, 44, 44)	-0.75 (± 8.69)	-0.56 (± 7.35)	-0.52 (± 10.55)	1.85 (± 9.67)
Week 28 (44, 39, 40, 44)	-1.18 (± 8.27)	-0.05 (± 8.51)	-0.05 (± 9.97)	1.61 (± 10.55)
Week 32 (41, 40, 43, 42)	-1.59 (± 7.69)	-2.56 (± 6.51)	-0.16 (± 7.70)	0.70 (± 8.74)
Week 40 (41, 42, 40, 43)	-2.60 (± 9.18)	-2.02 (± 5.99)	-1.36 (± 10.12)	0.33 (± 8.41)
Week 48 (37, 41, 39, 41)	-1.46 (± 11.29)	-3.71 (± 7.41)	-0.84 (± 9.42)	1.69 (± 10.05)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Monocytes

End point title	Mean change from baseline in Monocytes

End point description:

Monocytes was measured in number of monocytes per liter (10^9/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: 10^9 monocytes per liter				
arithmetic mean (standard deviation)				
Week 2 (42, 39, 44, 41)	-0.01 (± 0.17)	0.01 (± 0.18)	0.05 (± 0.14)	0.01 (± 0.13)
Week 4 (43, 43, 41, 46)	0.01 (± 0.18)	0.04 (± 0.18)	0.01 (± 0.14)	0.06 (± 0.19)
Week 8 (42, 41, 43, 43)	-0.03 (± 0.18)	0.04 (± 0.18)	0.03 (± 0.16)	0.02 (± 0.17)
Week 12 (44, 40, 44, 42)	-0.01 (± 0.19)	0.00 (± 0.14)	0.04 (± 0.18)	0.06 (± 0.15)
Week 16 (43, 42, 43, 44)	-0.01 (± 0.17)	0.01 (± 0.17)	0.05 (± 0.18)	0.03 (± 0.14)
Week 20 (42, 40, 40, 42)	-0.03 (± 0.19)	0.00 (± 0.16)	0.00 (± 0.13)	0.05 (± 0.19)
Week 24 (41, 40, 44, 44)	0.00 (± 0.19)	0.04 (± 0.19)	0.03 (± 0.17)	0.00 (± 0.17)
Week 28 (44, 39, 40, 44)	0.00 (± 0.20)	0.04 (± 0.21)	0.08 (± 0.19)	0.02 (± 0.17)
Week 32 (41, 40, 43, 42)	-0.01 (± 0.18)	0.02 (± 0.19)	0.05 (± 0.23)	-0.01 (± 0.19)
Week 40 (41, 42, 40, 43)	0.03 (± 0.17)	0.05 (± 0.16)	0.04 (± 0.16)	-0.01 (± 0.18)
Week 48 (37, 41, 39, 41)	-0.02 (± 0.20)	-0.01 (± 0.13)	0.03 (± 0.15)	-0.02 (± 0.18)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Monocytes/Leukocytes

End point title	Mean change from baseline in Monocytes/Leukocytes

End point description:

Monocytes/Leukocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: % of Monocytes per Leukocytes				
arithmetic mean (standard deviation)				
Week 2 (42, 39, 44, 41)	-0.87 (± 2.50)	-0.07 (± 2.46)	0.23 (± 3.03)	-0.37 (± 2.25)
Week 4 (43, 43, 41, 46)	0.26 (± 3.30)	0.27 (± 2.41)	-0.16 (± 3.11)	-0.24 (± 2.82)
Week 8 (42, 41, 43, 43)	-0.21 (± 3.47)	0.07 (± 3.61)	0.51 (± 3.83)	0.08 (± 3.12)
Week 12 (44, 40, 44, 42)	0.07 (± 2.79)	-0.11 (± 2.38)	0.22 (± 3.37)	0.45 (± 2.74)
Week 16 (43, 42, 43, 44)	0.06 (± 3.30)	0.59 (± 2.85)	0.43 (± 3.31)	0.28 (± 3.13)
Week 20 (42, 40, 40, 42)	-0.27 (± 3.84)	0.56 (± 3.08)	0.33 (± 3.81)	0.43 (± 3.39)
Week 24 (41, 40, 44, 44)	0.06 (± 3.45)	0.84 (± 2.97)	0.46 (± 3.00)	0.41 (± 3.24)
Week 28 (44, 39, 40, 44)	-0.24 (± 3.54)	0.69 (± 3.24)	0.64 (± 3.67)	0.94 (± 3.78)
Week 32 (41, 40, 43, 42)	-0.08 (± 3.11)	0.13 (± 2.62)	0.46 (± 3.91)	-0.03 (± 3.76)
Week 40 (41, 42, 40, 43)	0.49 (± 3.55)	0.64 (± 2.92)	0.83 (± 3.69)	0.59 (± 3.07)
Week 48 (37, 41, 39, 41)	-0.04 (± 3.79)	-0.13 (± 2.41)	0.47 (± 3.82)	0.29 (± 3.30)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Neutrophils

End point title	Mean change from baseline in Neutrophils

End point description:

Neutrophils was measured in number of neutrophils per liter (10^9/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: 10^9 neutrophils per liter				
arithmetic mean (standard deviation)				
Week 2 (43, 39, 44, 41)	0.28 (± 2.43)	0.26 (± 1.17)	0.17 (± 1.33)	-0.01 (± 1.46)
Week 4 (43, 43, 41, 46)	0.07 (± 1.82)	0.27 (± 1.40)	0.21 (± 1.64)	0.23 (± 1.96)
Week 8 (42, 41, 43, 43)	-0.13 (± 2.20)	0.41 (± 1.32)	-0.07 (± 1.53)	-0.20 (± 1.49)
Week 12 (44, 41, 44, 42)	-0.24 (± 1.56)	0.20 (± 1.65)	0.10 (± 1.94)	-0.01 (± 2.03)
Week 16 (43, 42, 43, 44)	-0.22 (± 2.13)	0.20 (± 1.41)	0.15 (± 1.61)	-0.20 (± 2.14)
Week 20 (42, 41, 40, 42)	-0.07 (± 2.21)	0.01 (± 1.22)	-0.39 (± 1.69)	0.09 (± 2.51)
Week 24 (41, 40, 44, 44)	-0.12 (± 2.24)	-0.06 (± 1.54)	-0.16 (± 1.77)	-0.38 (± 1.92)
Week 28 (44, 39, 40, 44)	0.04 (± 1.81)	0.13 (± 1.64)	0.10 (± 1.91)	-0.62 (± 1.78)
Week 32 (41, 40, 43, 42)	-0.07 (± 1.87)	0.33 (± 1.27)	0.07 (± 1.54)	-0.40 (± 1.67)
Week 40 (41, 42, 40, 43)	0.16 (± 2.37)	0.16 (± 1.31)	-0.32 (± 1.57)	-0.41 (± 1.88)
Week 48 (37, 41, 39, 41)	-0.29 (± 1.58)	0.55 (± 1.15)	-0.09 (± 2.02)	-0.54 (± 1.78)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Neutrophils/Leukocytes

End point title	Mean change from baseline in Neutrophils/Leukocytes

End point description:

Neutrophils/Leukocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: % of Neutrophils per Leukocytes				
arithmetic mean (standard deviation)				
Week 2 (42, 39, 44, 41)	2.99 (± 10.73)	-0.21 (± 7.94)	-1.20 (± 8.40)	-1.93 (± 8.18)
Week 4 (43, 43, 41, 46)	0.91 (± 9.37)	0.89 (± 7.82)	1.47 (± 12.70)	-0.37 (± 10.27)
Week 8 (42, 41, 43, 43)	2.15 (± 12.95)	0.79 (± 8.80)	-1.17 (± 13.28)	-2.23 (± 10.92)
Week 12 (44, 40, 44, 42)	-0.52 (± 9.44)	-1.25 (± 11.78)	-0.12 (± 13.18)	-2.90 (± 12.85)
Week 16 (43, 42, 43, 44)	0.77 (± 11.02)	0.54 (± 8.50)	0.56 (± 12.48)	-0.24 (± 12.23)

Week 20 (42, 40, 40, 42)	2.22 (± 13.21)	-0.73 (± 8.42)	-1.25 (± 14.29)	-0.71 (± 13.91)
Week 24 (41, 40, 44, 44)	0.65 (± 11.48)	-1.25 (± 8.74)	0.10 (± 13.20)	-2.30 (± 12.41)
Week 28 (44, 39, 40, 44)	1.28 (± 10.38)	-0.88 (± 10.56)	-0.77 (± 13.27)	-2.60 (± 13.79)
Week 32 (41, 40, 43, 42)	1.67 (± 9.93)	2.15 (± 7.42)	-0.47 (± 9.80)	-0.48 (± 12.08)
Week 40 (41, 42, 40, 43)	2.29 (± 11.66)	1.36 (± 6.95)	0.07 (± 13.23)	-0.93 (± 11.50)
Week 48 (37, 41, 39, 41)	1.41 (± 13.58)	4.09 (± 8.40)	0.30 (± 12.47)	-2.28 (± 12.38)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Platelets

End point title	Mean change from baseline in Platelets

End point description:

Platelets was measured in number of platelets per liter (10^9/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: 10^9 platelets per liter				
arithmetic mean (standard deviation)				
Week 2 (41, 42, 45, 42)	5.9 (± 33.2)	10.0 (± 40.0)	1.4 (± 47.5)	-1.0 (± 52.0)
Week 4 (43, 44, 43, 46)	-5.2 (± 51.3)	0.0 (± 32.4)	4.9 (± 43.8)	8.1 (± 42.6)
Week 8 (42, 44, 44, 44)	0.2 (± 45.3)	-0.3 (± 40.3)	3.9 (± 52.0)	-6.4 (± 40.5)
Week 12 (43, 43, 43, 44)	-4.3 (± 50.6)	-1.7 (± 38.8)	-2.7 (± 49.0)	1.8 (± 49.4)
Week 16 (44, 43, 43, 45)	0.7 (± 57.7)	-0.7 (± 40.5)	-1.5 (± 66.7)	-2.3 (± 68.1)
Week 20 (42, 43, 41, 42)	9.2 (± 57.1)	-3.3 (± 43.0)	0.5 (± 44.6)	0.8 (± 64.4)
Week 24 (42, 41, 44, 43)	0.2 (± 60.2)	-5.2 (± 43.8)	2.4 (± 68.6)	1.7 (± 67.0)
Week 28 (42, 41, 41, 44)	3.6 (± 64.6)	1.8 (± 52.6)	-5.8 (± 71.9)	1.5 (± 64.4)
Week 32 (42, 42, 42, 40)	4.0 (± 71.8)	-1.9 (± 55.4)	-4.6 (± 57.5)	9.9 (± 93.8)
Week 40 (42, 43, 41, 43)	10.3 (± 74.9)	14.2 (± 52.7)	-8.8 (± 63.2)	-1.5 (± 67.4)
Week 48 (37, 42, 39, 42)	7.1 (± 67.4)	3.5 (± 58.2)	-9.5 (± 70.9)	-8.8 (± 66.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in cluster of differentiation 3 (CD3)

End point title	Mean change from baseline in cluster of differentiation 3 (CD3)

End point description:

Cluster of differentiation 3 (CD3) was measured in cells per microliter (cells/µL). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: cells/µL				
arithmetic mean (standard deviation)				
Week 2 (38, 40, 42, 40)	33.0 (± 313.6)	77.7 (± 383.6)	106.6 (± 283.1)	126.9 (± 338.9)
Week 4 (39, 40, 40, 39)	-30.6 (± 293.5)	-47.7 (± 504.3)	24.0 (± 394.9)	227.2 (± 412.1)
Week 8 (38, 40, 39, 40)	-64.7 (± 405.7)	-58.6 (± 422.8)	-20.5 (± 403.2)	78.3 (± 560.0)
Week 12 (41, 41, 40, 40)	-44.2 (± 283.2)	-48.8 (± 452.1)	-57.8 (± 385.1)	43.7 (± 599.3)
Week 16 (38, 42, 38, 42)	-81.9 (± 479.4)	-141.2 (± 516.1)	-4.5 (± 383.2)	-45.4 (± 520.8)
Week 20 (40, 40, 39, 42)	-92.7 (± 391.1)	-173.4 (± 490.9)	5.9 (± 352.9)	-89.9 (± 577.7)
Week 24 (39, 39, 42, 43)	-85.8 (± 472.5)	-128.9 (± 569.4)	-88.5 (± 462.1)	-78.3 (± 570.7)
Week 28 (41, 40, 39, 38)	-27.6 (± 507.3)	-81.2 (± 652.7)	46.1 (± 482.2)	7.4 (± 561.2)
Week 32 (41, 41, 41, 41)	-70.9 (± 428.4)	-173.6 (± 565.8)	18.0 (± 415.0)	-90.5 (± 504.0)
Week 40 (40, 41, 39, 43)	-110.5 (± 526.4)	-166.9 (± 542.2)	-1.8 (± 410.7)	31.7 (± 528.8)
Week 48 (35, 40, 35, 41)	-115.6 (± 581.1)	-253.1 (± 637.0)	36.1 (± 492.3)	22.3 (± 558.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in CD3/Lymphocytes

End point title	Mean change from baseline in CD3/Lymphocytes

End point description:

CD3/Lymphocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: % of CD3 per Leukocytes				
arithmetic mean (standard deviation)				
Week 2 (38, 40, 42, 40)	-0.7 (± 6.1)	-0.9 (± 4.6)	-2.0 (± 5.7)	-0.2 (± 7.8)
Week 4 (39, 40, 40, 39)	-2.1 (± 7.3)	-0.5 (± 6.0)	-1.9 (± 5.0)	-0.5 (± 6.8)
Week 8 (38, 40, 39, 40)	-0.9 (± 6.1)	-1.2 (± 4.8)	-2.6 (± 5.9)	0.6 (± 9.5)
Week 12 (41, 41, 40, 40)	-0.4 (± 5.6)	-1.1 (± 8.2)	-2.4 (± 6.0)	-0.1 (± 9.2)
Week 16 (38, 42, 38, 42)	-1.9 (± 5.8)	-1.6 (± 7.8)	-1.9 (± 7.6)	-1.4 (± 7.9)
Week 20 (40, 40, 39, 42)	-0.8 (± 5.0)	0.0 (± 8.6)	-2.3 (± 6.9)	0.6 (± 9.2)
Week 24 (39, 39, 42, 43)	0.0 (± 6.5)	-0.1 (± 8.8)	-1.8 (± 6.6)	18.7 (± 114.3)
Week 28 (41, 40, 39, 38)	-0.2 (± 6.9)	0.2 (± 8.3)	-2.9 (± 7.2)	0.9 (± 10.2)
Week 32 (41, 41, 41, 41)	-1.3 (± 7.0)	0.2 (± 7.9)	-1.8 (± 6.8)	1.4 (± 8.5)
Week 40 (40, 41, 39, 43)	0.2 (± 6.7)	1.4 (± 6.9)	0.5 (± 6.5)	3.3 (± 7.9)
Week 48 (35, 40, 35, 41)	1.3 (± 8.0)	0.3 (± 7.6)	0.1 (± 6.2)	4.5 (± 7.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in cluster of differentiation 19 (CD19)

End point title	Mean change from baseline in cluster of differentiation 19 (CD19)

End point description:

Cluster of differentiation 19 (CD19) was measured in cells per microliter (cells/µL). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: cells/µL				
arithmetic mean (standard deviation)				
Week 2 (38, 40, 42, 40)	9.6 (± 56.7)	12.3 (± 76.2)	24.8 (± 71.0)	63.4 (± 133.5)
Week 4 (39, 40, 40, 39)	-2.8 (± 46.3)	-31.2 (± 177.0)	9.2 (± 60.5)	82.8 (± 154.5)
Week 8 (38, 40, 39, 40)	-13.3 (± 72.9)	-29.4 (± 183.5)	8.7 (± 70.8)	19.4 (± 146.4)
Week 12 (41, 41, 40, 40)	-2.6 (± 83.4)	-48.1 (± 207.1)	-17.9 (± 77.8)	53.2 (± 203.6)
Week 16 (38, 42, 38, 42)	-12.5 (± 84.3)	-50.1 (± 201.5)	-10.0 (± 92.4)	13.2 (± 147.8)
Week 20 (40, 40, 39, 42)	-15.1 (± 86.0)	-75.4 (± 216.6)	-2.5 (± 57.1)	2.7 (± 132.6)
Week 24 (39, 39, 42, 43)	-15.0 (± 89.3)	-77.2 (± 231.9)	-20.3 (± 72.0)	-1.1 (± 135.0)
Week 28 (41, 40, 39, 38)	-20.6 (± 106.7)	-69.6 (± 206.7)	-13.1 (± 84.5)	-13.0 (± 123.2)
Week 32 (41, 41, 41, 41)	-14.3 (± 106.3)	-75.8 (± 225.7)	-10.4 (± 93.0)	-20.9 (± 168.1)
Week 40 (40, 41, 39, 43)	-24.8 (± 103.3)	-68.6 (± 211.0)	-26.9 (± 83.0)	-46.9 (± 138.0)
Week 48 (35, 40, 35, 41)	-37.0 (± 132.7)	-82.4 (± 243.7)	-15.5 (± 83.2)	-41.2 (± 120.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in CD19/Lymphocytes

End point title	Mean change from baseline in CD19/Lymphocytes

End point description:

CD19/Lymphocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: % of CD19 per Leukocytes				
arithmetic mean (standard deviation)				
Week 2 (38, 40, 42, 40)	-0.3 (± 2.1)	-0.1 (± 3.0)	1.0 (± 3.5)	1.5 (± 5.9)

Week 4 (39, 40, 40, 39)	0.0 (± 2.9)	-0.5 (± 3.7)	0.7 (± 3.3)	2.8 (± 5.7)
Week 8 (38, 40, 39, 40)	0.1 (± 2.8)	-0.5 (± 4.2)	0.7 (± 2.5)	0.4 (± 6.4)
Week 12 (41, 41, 40, 40)	-0.2 (± 3.2)	-1.0 (± 3.9)	-0.4 (± 3.1)	1.7 (± 7.9)
Week 16 (38, 42, 38, 42)	0.0 (± 4.7)	-1.2 (± 5.0)	-0.4 (± 3.3)	0.7 (± 5.9)
Week 20 (40, 40, 39, 42)	-0.4 (± 3.8)	-2.1 (± 6.2)	-0.3 (± 3.0)	-0.2 (± 6.9)
Week 24 (39, 39, 42, 43)	-0.9 (± 4.5)	-2.0 (± 6.5)	-0.6 (± 3.3)	-0.3 (± 7.3)
Week 28 (41, 40, 39, 38)	-1.2 (± 5.4)	-2.5 (± 5.9)	-1.1 (± 3.3)	-1.0 (± 6.6)
Week 32 (41, 41, 41, 41)	-0.4 (± 4.7)	-2.4 (± 5.5)	-0.6 (± 4.4)	-1.6 (± 6.3)
Week 40 (40, 41, 39, 43)	-1.2 (± 4.7)	-2.6 (± 5.4)	-1.9 (± 4.2)	-3.4 (± 6.7)
Week 48 (35, 40, 35, 41)	-1.2 (± 6.8)	-2.6 (± 7.2)	-1.6 (± 4.9)	-3.3 (± 6.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Aspartate Aminotransferase

End point title	Mean change from baseline in Aspartate Aminotransferase

End point description:

Aspartate Aminotransferase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: U/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 43)	-0.5 (± 8.8)	0.2 (± 8.0)	4.3 (± 43.1)	0.0 (± 7.2)
Week 4 (44, 44, 43, 46)	-0.1 (± 11.2)	0.2 (± 7.4)	-1.1 (± 7.6)	-1.9 (± 8.0)
Week 8 (44, 43, 44, 44)	-0.1 (± 8.7)	-1.5 (± 6.2)	0.5 (± 13.0)	-1.1 (± 8.1)
Week 12 (44, 44, 45, 44)	5.1 (± 27.0)	0.9 (± 6.2)	-1.8 (± 10.0)	-2.9 (± 7.1)
Week 16 (44, 44, 43, 45)	0.4 (± 7.7)	0.0 (± 6.3)	-2.3 (± 11.6)	-2.8 (± 8.4)
Week 20 (43, 43, 41, 44)	4.1 (± 24.1)	1.0 (± 11.5)	-0.7 (± 13.8)	-3.8 (± 8.1)
Week 24 (42, 43, 44, 44)	0.6 (± 11.8)	1.6 (± 10.4)	-1.8 (± 11.5)	-3.8 (± 8.4)
Week 28 (43, 42, 40, 42)	0.0 (± 12.3)	0.0 (± 10.2)	-1.5 (± 11.1)	-3.4 (± 9.1)
Week 32 (44, 44, 43, 44)	-0.3 (± 11.0)	0.3 (± 6.8)	-0.7 (± 12.9)	-3.4 (± 9.2)
Week 40 (42, 42, 41, 44)	-0.6 (± 10.2)	0.1 (± 9.1)	-0.3 (± 11.5)	-1.5 (± 9.8)
Week 48 (38, 42, 40, 43)	1.1 (± 10.8)	0.1 (± 13.1)	1.4 (± 13.4)	-2.1 (± 8.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Alanine Aminotransferase

End point title	Mean change from baseline in Alanine Aminotransferase

End point description:

Alanine Aminotransferase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: U/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 43)	2.4 (± 14.1)	2.6 (± 10.6)	0.5 (± 11.1)	-0.1 (± 8.6)
Week 4 (44, 44, 43, 46)	0.8 (± 9.9)	-0.5 (± 8.5)	0.9 (± 7.4)	0.3 (± 8.2)
Week 8 (44, 43, 44, 44)	0.2 (± 10.2)	-0.8 (± 8.3)	5.3 (± 28.8)	-0.6 (± 9.6)
Week 12 (44, 44, 45, 44)	7.0 (± 21.3)	0.8 (± 14.3)	-0.8 (± 8.1)	-0.1 (± 7.6)
Week 16 (44, 44, 43, 45)	1.5 (± 13.3)	-0.4 (± 9.3)	0.0 (± 10.3)	-1.1 (± 7.8)
Week 20 (43, 43, 42, 44)	5.3 (± 23.6)	-0.2 (± 10.2)	1.4 (± 10.8)	-3.7 (± 6.3)
Week 24 (42, 43, 44, 44)	3.1 (± 20.9)	0.5 (± 14.1)	2.0 (± 12.0)	-2.8 (± 7.7)
Week 28 (43, 42, 40, 42)	1.0 (± 13.9)	0.7 (± 10.5)	-0.4 (± 9.3)	-2.7 (± 7.2)
Week 32 (44, 44, 43, 44)	1.2 (± 13.4)	-0.5 (± 10.3)	1.3 (± 10.8)	-3.2 (± 6.1)
Week 40 (42, 42, 41, 44)	-0.5 (± 13.4)	2.6 (± 12.8)	3.0 (± 12.9)	-0.7 (± 8.3)
Week 48 (38, 42, 40, 43)	0.4 (± 11.5)	-1.2 (± 10.4)	3.5 (± 17.0)	-1.1 (± 7.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Alkaline Phosphatase

End point title	Mean change from baseline in Alkaline Phosphatase

End point description:

Alkaline Phosphatase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: U/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 44)	1.8 (± 10.7)	2.4 (± 10.6)	1.5 (± 8.0)	-3.6 (± 10.1)
Week 4 (44, 44, 43, 46)	-1.7 (± 9.7)	0.7 (± 9.2)	-0.7 (± 8.4)	-4.7 (± 9.4)
Week 8 (44, 43, 44, 44)	1.7 (± 12.9)	2.4 (± 12.7)	1.8 (± 15.6)	-6.1 (± 11.0)
Week 12 (44, 44, 45, 44)	2.2 (± 11.6)	4.2 (± 16.4)	1.9 (± 12.9)	-4.4 (± 11.8)
Week 16 (44, 45, 43, 45)	3.1 (± 10.7)	2.7 (± 13.0)	0.0 (± 10.4)	-6.7 (± 12.8)
Week 20 (43, 45, 42, 44)	3.9 (± 14.0)	1.4 (± 11.8)	1.4 (± 11.8)	-7.4 (± 11.2)
Week 24 (42, 43, 44, 44)	4.7 (± 15.0)	3.7 (± 14.0)	2.8 (± 11.6)	-2.7 (± 14.0)
Week 28 (43, 43, 40, 43)	2.8 (± 14.0)	3.1 (± 14.2)	1.9 (± 9.5)	-2.1 (± 13.5)
Week 32 (44, 44, 43, 45)	3.8 (± 14.6)	2.7 (± 16.0)	3.2 (± 12.1)	1.0 (± 15.9)
Week 40 (42, 42, 41, 44)	2.4 (± 17.1)	1.3 (± 13.1)	2.7 (± 13.0)	-3.0 (± 18.0)
Week 48 (38, 42, 40, 43)	2.6 (± 13.3)	4.0 (± 16.8)	5.5 (± 12.8)	-4.5 (± 18.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Gamma Glutamyl Transferase

End point title	Mean change from baseline in Gamma Glutamyl Transferase

End point description:

Gamma Glutamyl Transferase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: U/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 43)	0.3 (± 7.6)	2.0 (± 11.5)	8.8 (± 68.9)	-3.4 (± 24.3)
Week 4 (44, 44, 43, 46)	2.1 (± 8.7)	-1.3 (± 8.8)	2.7 (± 28.5)	-6.5 (± 35.5)
Week 8 (44, 43, 44, 44)	3.5 (± 23.0)	0.3 (± 10.5)	-2.8 (± 49.3)	-9.2 (± 43.3)
Week 12 (44, 44, 45, 44)	4.1 (± 21.0)	0.5 (± 13.4)	-5.1 (± 29.3)	-8.3 (± 46.1)

Week 16 (44, 45, 43, 45)	6.5 (± 20.2)	2.1 (± 12.5)	-6.1 (± 45.0)	-10.6 (± 47.7)
Week 20 (43, 44, 42, 44)	3.5 (± 14.1)	0.2 (± 13.4)	-3.7 (± 50.3)	-8.5 (± 50.5)
Week 24 (42, 43, 44, 44)	7.1 (± 22.0)	4.0 (± 18.7)	-0.4 (± 53.1)	-9.5 (± 47.2)
Week 28 (43, 43, 40, 43)	4.6 (± 25.7)	2.2 (± 18.3)	-7.0 (± 46.8)	0.0 (± 23.1)
Week 32 (44, 44, 43, 45)	4.4 (± 28.6)	1.5 (± 16.7)	-5.9 (± 44.5)	-8.2 (± 37.4)
Week 40 (42, 42, 41, 44)	3.4 (± 41.3)	5.7 (± 32.4)	0.4 (± 10.1)	-9.1 (± 45.3)
Week 48 (38, 42, 40,43)	1.8 (± 11.4)	5.3 (± 23.9)	4.7 (± 21.6)	-9.8 (± 44.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Bilirubin

End point title	Mean change from baseline in Bilirubin

End point description:

Bilirubin was measured in micromols per liter (µmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: µmol/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 43)	0.35 (± 2.72)	-0.48 (± 2.71)	0.28 (± 2.38)	-0.78 (± 3.13)
Week 4 (44, 44, 43, 46)	0.07 (± 2.50)	-0.18 (± 2.09)	-0.05 (± 2.14)	-0.79 (± 2.80)
Week 8 (44, 43, 44, 44)	-0.09 (± 2.66)	-0.69 (± 2.22)	-0.19 (± 2.13)	-0.23 (± 2.80)
Week 12 (44, 44, 45, 44)	-0.04 (± 2.60)	-0.70 (± 2.74)	0.37 (± 2.17)	-0.33 (± 3.28)
Week 16 (44, 45, 43, 45)	0.06 (± 2.41)	-0.45 (± 2.43)	-0.20 (± 2.71)	-0.51 (± 3.64)
Week 20 (43, 43, 42, 44)	-0.54 (± 2.89)	-0.38 (± 2.51)	0.51 (± 2.81)	-0.30 (± 3.03)
Week 24 (42, 43, 44, 44)	0.08 (± 2.75)	-0.14 (± 2.86)	0.54 (± 2.18)	-0.38 (± 3.57)
Week 28 (43, 42, 40, 42)	-0.10 (± 2.98)	-0.26 (± 3.23)	0.79 (± 2.71)	-0.82 (± 2.61)
Week 32 (44, 44, 43, 44)	0.09 (± 2.75)	-0.38 (± 2.61)	0.93 (± 3.18)	-0.38 (± 3.61)
Week 40 (42, 42, 41, 44)	-0.26 (± 3.70)	0.07 (± 3.18)	1.03 (± 2.35)	-0.15 (± 2.64)
Week 48 (38, 42, 40, 43)	0.69 (± 3.57)	-0.50 (± 3.12)	0.79 (± 3.04)	-0.20 (± 2.52)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Direct Bilirubin

End point title	Mean change from baseline in Direct Bilirubin

End point description:

Direct Bilirubin was measured in micromols per liter (µmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: µmol/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 43)	0.03 (± 0.92)	-0.06 (± 0.92)	0.09 (± 1.12)	-0.24 (± 1.10)
Week 4 (44, 44, 43, 46)	0.10 (± 1.03)	0.03 (± 0.75)	-0.04 (± 0.82)	-0.10 (± 0.93)
Week 8 (44, 43, 44, 44)	0.03 (± 0.91)	-0.18 (± 0.55)	-0.17 (± 0.86)	0.03 (± 1.10)
Week 12 (44, 44, 45, 44)	0.15 (± 0.99)	-0.07 (± 0.95)	-0.01 (± 1.06)	-0.05 (± 1.30)
Week 16 (44, 45, 43, 45)	0.18 (± 0.81)	-0.01 (± 0.66)	-0.07 (± 1.04)	-0.01 (± 1.40)
Week 20 (43, 43, 42, 44)	-0.04 (± 0.95)	0.07 (± 0.91)	0.02 (± 0.94)	0.00 (± 1.19)
Week 24 (42, 43, 44, 44)	0.05 (± 1.10)	0.14 (± 0.95)	0.08 (± 1.02)	-0.08 (± 1.25)
Week 28 (43, 42, 40, 42)	0.06 (± 1.06)	-0.06 (± 1.00)	0.11 (± 0.80)	-0.06 (± 1.15)
Week 32 (44, 44, 43, 44)	0.12 (± 1.16)	0.05 (± 0.90)	0.21 (± 1.21)	-0.04 (± 1.36)
Week 40 (42, 42, 41, 44)	0.07 (± 1.31)	0.03 (± 0.76)	0.23 (± 1.00)	0.07 (± 1.05)
Week 48 (38, 42, 40, 43)	0.31 (± 1.34)	-0.05 (± 1.01)	0.20 (± 1.25)	0.08 (± 0.98)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Lactate Dehydrogenase

End point title	Mean change from baseline in Lactate Dehydrogenase

End point description:

Lactate Dehydrogenase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: U/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 44)	-3.3 (± 27.8)	-7.8 (± 21.2)	-5.9 (± 35.2)	-12.8 (± 24.8)
Week 4 (44, 44, 43, 46)	-3.0 (± 23.4)	-3.7 (± 37.0)	-5.6 (± 35.6)	-18.5 (± 34.1)
Week 8 (44, 43, 44, 44)	-5.7 (± 27.4)	-11.8 (± 31.5)	-9.2 (± 39.0)	-20.4 (± 37.4)
Week 12 (44, 44, 45, 44)	3.0 (± 28.7)	-7.4 (± 34.6)	-11.1 (± 45.1)	-24.4 (± 39.0)
Week 16 (44, 44, 43, 45)	-2.2 (± 25.5)	-11.1 (± 29.9)	-10.6 (± 48.6)	-22.4 (± 43.3)
Week 20 (43, 45, 41, 44)	-0.7 (± 33.9)	-10.8 (± 37.0)	-9.9 (± 47.8)	-28.5 (± 32.1)
Week 24 (42, 43, 44, 44)	-4.5 (± 31.3)	-14.3 (± 31.5)	-14.6 (± 34.4)	-29.3 (± 32.2)
Week 28 (43, 43, 40, 43)	0.0 (± 40.8)	-16.0 (± 40.9)	-13.2 (± 35.0)	-34.8 (± 36.9)
Week 32 (44, 44, 43, 45)	5.0 (± 55.0)	-9.9 (± 43.4)	-8.1 (± 33.5)	-22.9 (± 40.6)
Week 40 (42, 42, 41, 44)	-1.6 (± 38.1)	-2.9 (± 41.1)	-8.0 (± 28.4)	-20.5 (± 40.1)
Week 48 (38, 42, 40, 43)	-8.8 (± 35.2)	-4.2 (± 54.3)	-1.5 (± 32.7)	-16.0 (± 36.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Creatinine

End point title	Mean change from baseline in Creatinine

End point description:

Creatinine was measured in micromols per liter (µmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: µmol/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 44)	0.9 (± 9.1)	-0.1 (± 8.0)	1.5 (± 5.8)	0.6 (± 7.2)
Week 4 (44, 44, 43, 46)	-0.8 (± 8.9)	-0.2 (± 9.3)	-0.6 (± 7.3)	-1.4 (± 8.2)
Week 8 (44, 43, 44, 44)	0.5 (± 7.0)	0.3 (± 7.6)	-0.5 (± 6.9)	0.1 (± 8.4)
Week 12 (44, 44, 45, 44)	-0.3 (± 7.0)	1.4 (± 7.5)	-0.4 (± 6.4)	-0.7 (± 8.2)
Week 16 (44, 45, 43, 45)	-0.1 (± 9.8)	1.0 (± 8.2)	0.7 (± 6.8)	-1.1 (± 9.4)
Week 20 (43, 45, 42, 44)	0.7 (± 8.6)	1.4 (± 10.2)	0.8 (± 6.9)	-0.3 (± 7.7)
Week 24 (42, 43, 44, 44)	0.0 (± 8.8)	0.8 (± 8.8)	0.3 (± 6.6)	0.9 (± 9.7)
Week 28 (43, 43, 40, 43)	2.5 (± 10.0)	2.7 (± 10.0)	1.0 (± 7.8)	-0.9 (± 7.8)

Week 32 (44, 44, 43, 45)	5.5 (± 35.7)	0.5 (± 8.1)	3.6 (± 7.8)	1.6 (± 11.2)
Week 40 (42, 42, 41, 44)	2.3 (± 9.5)	2.2 (± 8.5)	3.9 (± 6.0)	3.0 (± 8.4)
Week 48 (38, 42, 40, 43)	1.9 (± 10.6)	0.7 (± 7.6)	2.5 (± 5.2)	2.9 (± 9.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Urea Nitrogen

End point title	Mean change from baseline in Urea Nitrogen

End point description:

Urea Nitrogen was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 43)	0.28 (± 1.55)	-0.09 (± 1.23)	-0.05 (± 1.32)	-0.02 (± 1.31)
Week 4 (44, 44, 43, 46)	-0.07 (± 1.21)	-0.33 (± 1.52)	-0.14 (± 1.20)	0.04 (± 1.19)
Week 8 (44, 43, 44, 44)	0.06 (± 1.25)	-0.26 (± 1.22)	-0.19 (± 1.07)	0.17 (± 1.59)
Week 12 (44, 44, 45, 44)	0.03 (± 1.13)	-0.39 (± 1.31)	-0.29 (± 1.17)	-0.22 (± 1.15)
Week 16 (44, 45, 43, 45)	0.19 (± 1.35)	-0.18 (± 1.40)	0.19 (± 1.49)	-0.03 (± 1.41)
Week 20 (43, 44, 42, 44)	-0.18 (± 1.29)	-0.20 (± 1.33)	-0.25 (± 1.22)	-0.16 (± 1.08)
Week 24 (42, 43, 44, 44)	0.08 (± 1.69)	-0.44 (± 1.38)	-0.13 (± 1.18)	-0.09 (± 1.50)
Week 28 (43, 43, 40, 43)	0.13 (± 1.38)	0.03 (± 1.61)	-0.23 (± 1.26)	-0.22 (± 1.14)
Week 32 (44, 44, 43, 45)	0.40 (± 2.37)	-0.30 (± 1.65)	0.21 (± 1.17)	0.10 (± 1.43)
Week 40 (42, 42, 41, 44)	0.29 (± 1.54)	0.10 (± 1.73)	0.21 (± 1.20)	0.14 (± 1.43)
Week 48 (38, 42, 40, 43)	0.05 (± 1.22)	-0.31 (± 1.54)	0.23 (± 1.38)	-0.02 (± 1.56)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Sodium

End point title	Mean change from baseline in Sodium

End point description:

Sodium was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study

participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 44)	-0.1 (± 1.9)	-0.4 (± 2.4)	0.1 (± 1.6)	0.0 (± 2.2)
Week 4 (44, 44, 43, 46)	-0.3 (± 2.0)	-0.6 (± 2.1)	0.3 (± 2.1)	-0.1 (± 2.4)
Week 8 (44, 43, 44, 44)	0.1 (± 2.2)	-0.4 (± 2.4)	0.3 (± 2.2)	0.1 (± 2.3)
Week 12 (44, 44, 45, 44)	-0.3 (± 2.0)	-0.5 (± 2.0)	0.2 (± 2.0)	0.1 (± 2.3)
Week 16 (44, 45, 43, 45)	-0.4 (± 2.3)	-0.2 (± 1.9)	0.0 (± 2.0)	-0.2 (± 2.3)
Week 20 (43, 45, 42, 44)	0.3 (± 2.2)	-0.8 (± 2.2)	-0.1 (± 2.0)	-0.5 (± 2.4)
Week 24 (42, 43, 44, 44)	-0.1 (± 2.5)	-0.4 (± 2.2)	0.0 (± 2.2)	-0.3 (± 2.1)
Week 28 (43, 43, 40, 43)	0.0 (± 1.9)	-0.4 (± 2.4)	0.2 (± 1.9)	0.1 (± 2.3)
Week 32 (44, 44, 43, 45)	0.0 (± 2.3)	-0.8 (± 3.2)	0.1 (± 2.1)	0.2 (± 2.2)
Week 40 (42, 42, 41, 44)	-0.1 (± 2.2)	-1.2 (± 2.2)	-0.1 (± 1.6)	-0.3 (± 2.4)
Week 48 (38, 42, 40, 43)	-0.4 (± 2.0)	-1.1 (± 2.6)	-0.5 (± 1.7)	0.2 (± 2.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Potassium

End point title	Mean change from baseline in Potassium

End point description:

Potassium was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 44, 44)	0.04 (± 0.45)	0.15 (± 0.40)	0.00 (± 0.36)	-0.03 (± 0.37)
Week 4 (44, 44, 43, 46)	0.06 (± 0.44)	0.08 (± 0.35)	-0.07 (± 0.41)	-0.12 (± 0.40)
Week 8 (44, 43, 44, 44)	-0.04 (± 0.40)	0.11 (± 0.38)	0.00 (± 0.35)	-0.07 (± 0.40)
Week 12 (44, 44, 44, 44)	-0.01 (± 0.33)	0.02 (± 0.31)	-0.07 (± 0.41)	-0.12 (± 0.34)
Week 16 (44, 44, 43, 45)	-0.01 (± 0.34)	0.16 (± 0.33)	-0.09 (± 0.42)	-0.05 (± 0.33)
Week 20 (43, 45, 40, 43)	0.04 (± 0.38)	0.14 (± 0.33)	-0.04 (± 0.46)	-0.08 (± 0.37)
Week 24 (42, 43, 43, 43)	0.06 (± 0.43)	0.07 (± 0.39)	0.03 (± 0.33)	-0.11 (± 0.37)
Week 28 (41, 43, 40, 43)	0.09 (± 0.43)	0.12 (± 0.47)	0.06 (± 0.42)	0.03 (± 0.45)
Week 32 (44, 44, 43, 45)	0.03 (± 0.44)	0.07 (± 0.44)	0.10 (± 0.46)	-0.05 (± 0.38)
Week 40 (42, 41, 41, 44)	0.06 (± 0.33)	0.16 (± 0.51)	0.16 (± 0.39)	-0.06 (± 0.37)
Week 48 (38, 42, 40, 43)	-0.01 (± 0.30)	0.00 (± 0.30)	-0.02 (± 0.39)	-0.07 (± 0.40)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Calcium

End point title	Mean change from baseline in Calcium

End point description:

Calcium was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 44)	0.008 (± 0.104)	-0.001 (± 0.103)	0.004 (± 0.088)	-0.008 (± 0.092)
Week 4 (44, 44, 43, 46)	0.007 (± 0.108)	-0.018 (± 0.099)	-0.018 (± 0.090)	-0.001 (± 0.086)
Week 8 (44, 43, 44, 44)	-0.006 (± 0.093)	-0.033 (± 0.117)	-0.014 (± 0.106)	-0.003 (± 0.089)
Week 12 (44, 44, 45, 44)	0.006 (± 0.108)	-0.011 (± 0.121)	-0.013 (± 0.097)	-0.004 (± 0.111)
Week 16 (44, 45, 43, 45)	-0.025 (± 0.106)	-0.004 (± 0.088)	-0.013 (± 0.095)	-0.024 (± 0.119)

Week 20 (43, 45, 42, 44)	-0.036 (± 0.116)	-0.020 (± 0.084)	-0.015 (± 0.108)	0.005 (± 0.080)
Week 24 (42, 43, 44, 44)	-0.027 (± 0.106)	-0.026 (± 0.094)	-0.012 (± 0.095)	0.007 (± 0.100)
Week 28 (43, 43, 40, 43)	-0.031 (± 0.121)	-0.039 (± 0.091)	-0.016 (± 0.113)	-0.014 (± 0.092)
Week 32 (44, 44, 43, 45)	0.003 (± 0.098)	-0.043 (± 0.099)	0.019 (± 0.107)	-0.001 (± 0.105)
Week 40 (42, 42, 41, 44)	-0.027 (± 0.114)	-0.022 (± 0.115)	0.006 (± 0.115)	-0.012 (± 0.105)
Week 48 (38, 42, 40, 43)	-0.013 (± 0.096)	-0.037 (± 0.119)	-0.004 (± 0.104)	-0.017 (± 0.110)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Phosphate

End point title	Mean change from baseline in Phosphate

End point description:

Phosphate was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 44, 43)	0.044 (± 0.163)	0.032 (± 0.192)	-0.047 (± 0.230)	0.033 (± 0.168)
Week 4 (44, 44, 43, 46)	-0.004 (± 0.162)	-0.029 (± 0.185)	-0.070 (± 0.187)	0.020 (± 0.163)
Week 8 (44, 43, 44, 44)	0.006 (± 0.178)	-0.063 (± 0.225)	-0.028 (± 0.207)	0.051 (± 0.187)
Week 12 (44, 44, 44, 44)	0.029 (± 0.159)	-0.004 (± 0.149)	-0.015 (± 0.236)	0.045 (± 0.183)
Week 16 (44, 44, 43, 45)	-0.010 (± 0.186)	0.012 (± 0.182)	-0.025 (± 0.195)	0.005 (± 0.178)
Week 20 (43, 43, 41, 43)	-0.030 (± 0.208)	-0.037 (± 0.244)	-0.031 (± 0.177)	0.013 (± 0.187)
Week 24 (42, 43, 43, 43)	-0.013 (± 0.181)	-0.042 (± 0.160)	-0.040 (± 0.229)	0.035 (± 0.200)
Week 28 (41, 42, 40, 42)	-0.024 (± 0.189)	0.008 (± 0.238)	-0.031 (± 0.232)	0.037 (± 0.184)
Week 32 (44, 44, 43, 44)	-0.002 (± 0.217)	-0.056 (± 0.223)	0.015 (± 0.220)	0.030 (± 0.190)

Week 40 (42, 41, 41, 44)	0.018 (± 0.207)	0.009 (± 0.196)	-0.022 (± 0.208)	0.034 (± 0.224)
Week 48 (38, 41, 40, 43)	0.032 (± 0.183)	-0.012 (± 0.167)	-0.044 (± 0.214)	0.035 (± 0.190)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Cholesterol

End point title	Mean change from baseline in Cholesterol

End point description:

Cholesterol was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 43)	0.00 (± 0.49)	-0.07 (± 0.46)	-0.06 (± 0.51)	-0.19 (± 0.47)
Week 4 (44, 44, 43, 46)	-0.08 (± 0.49)	-0.03 (± 0.46)	-0.07 (± 0.68)	-0.07 (± 0.57)
Week 8 (44, 43, 44, 44)	-0.09 (± 0.57)	-0.07 (± 0.46)	-0.15 (± 0.81)	-0.17 (± 0.59)
Week 12 (44, 44, 45, 44)	-0.14 (± 0.72)	-0.16 (± 0.61)	-0.23 (± 0.68)	-0.10 (± 0.75)
Week 16 (44, 45, 43, 45)	-0.16 (± 0.80)	-0.16 (± 0.66)	-0.35 (± 0.80)	-0.27 (± 0.72)
Week 20 (43, 44, 42, 44)	-0.27 (± 0.77)	-0.22 (± 0.60)	-0.42 (± 0.81)	-0.23 (± 0.85)
Week 24 (42, 43, 44, 44)	-0.12 (± 0.87)	-0.17 (± 0.66)	-0.28 (± 0.96)	-0.16 (± 0.78)
Week 28 (43, 43, 40, 43)	-0.17 (± 0.89)	-0.37 (± 0.63)	-0.35 (± 0.97)	-0.29 (± 0.80)
Week 32 (44, 44, 43, 45)	-0.13 (± 0.86)	-0.22 (± 0.63)	-0.16 (± 0.83)	-0.15 (± 0.81)
Week 40 (42, 42, 41, 44)	-0.34 (± 0.87)	-0.25 (± 0.80)	-0.19 (± 0.77)	-0.13 (± 1.15)
Week 48 (38, 42, 40, 43)	-0.40 (± 0.80)	-0.36 (± 0.74)	-0.23 (± 0.97)	-0.18 (± 1.09)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Triglycerides

End point title	Mean change from baseline in Triglycerides

End point description:

Triglycerides was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study

participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 44)	-0.176 (± 1.593)	0.046 (± 0.683)	0.110 (± 0.855)	0.183 (± 0.751)
Week 4 (44, 44, 43, 46)	-0.189 (± 1.212)	-0.004 (± 0.510)	-0.030 (± 0.471)	0.084 (± 0.529)
Week 8 (44, 43, 44, 44)	-0.182 (± 1.554)	0.076 (± 0.582)	-0.084 (± 0.498)	0.046 (± 0.585)
Week 12 (44, 44, 45, 44)	-0.265 (± 1.445)	0.088 (± 0.713)	0.063 (± 0.578)	0.009 (± 0.514)
Week 16 (44, 45, 43, 45)	-0.164 (± 1.345)	0.099 (± 1.488)	0.142 (± 0.580)	0.112 (± 1.035)
Week 20 (43, 45, 42, 44)	-0.233 (± 1.391)	-0.104 (± 0.837)	0.008 (± 0.622)	-0.060 (± 0.707)
Week 24 (42, 43, 44, 44)	-0.263 (± 1.515)	-0.045 (± 0.774)	-0.013 (± 0.608)	-0.030 (± 0.707)
Week 28 (43, 43, 40, 43)	-0.013 (± 1.559)	-0.125 (± 0.782)	-0.043 (± 0.423)	-0.036 (± 0.663)
Week 32 (44, 44, 43, 45)	-0.260 (± 1.418)	0.045 (± 0.717)	0.057 (± 0.532)	0.112 (± 0.718)
Week 40 (42, 42, 41, 44)	-0.134 (± 1.175)	-0.159 (± 0.765)	0.177 (± 0.821)	0.022 (± 0.644)
Week 48 (38, 42, 40, 43)	-0.242 (± 1.516)	-0.149 (± 0.758)	0.114 (± 0.507)	0.054 (± 0.752)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Protein

End point title	Mean change from baseline in Protein

End point description:

Protein was measured in grams per liter (g/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: g/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 44)	-0.2 (± 3.7)	-1.2 (± 4.0)	-1.0 (± 4.2)	-1.1 (± 3.8)
Week 4 (44, 44, 43, 46)	-1.5 (± 4.4)	-1.6 (± 4.2)	-1.5 (± 4.7)	-1.7 (± 4.4)
Week 8 (44, 43, 44, 44)	-1.1 (± 4.4)	-2.1 (± 4.1)	-1.8 (± 5.7)	-2.0 (± 3.9)
Week 12 (44, 44, 45, 44)	-0.8 (± 3.8)	-1.3 (± 4.7)	-1.4 (± 5.2)	-1.2 (± 5.8)
Week 16 (44, 45, 43, 45)	-1.2 (± 5.2)	-0.3 (± 4.1)	-2.3 (± 5.6)	-3.8 (± 5.0)
Week 20 (43, 45, 42, 44)	-2.7 (± 6.0)	-1.6 (± 4.6)	-2.6 (± 4.7)	-3.1 (± 5.4)
Week 24 (42, 43, 44, 44)	-2.2 (± 7.5)	-1.8 (± 4.6)	-1.8 (± 5.5)	-2.0 (± 4.7)
Week 28 (43, 43, 40, 43)	-3.1 (± 7.4)	-2.4 (± 4.6)	-2.5 (± 5.7)	-3.6 (± 6.4)
Week 32 (44, 44, 43, 45)	-1.4 (± 6.9)	-1.5 (± 5.7)	-0.8 (± 5.0)	-1.9 (± 6.4)
Week 40 (42, 42, 41, 44)	-2.2 (± 6.5)	-0.9 (± 5.0)	-1.8 (± 5.3)	-2.6 (± 6.1)
Week 48 (38, 42, 40, 43)	-2.3 (± 6.2)	-2.4 (± 5.9)	-0.9 (± 5.1)	-3.4 (± 6.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Albumin

End point title	Mean change from baseline in Albumin

End point description:

Albumin was measured in grams per liter (g/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: g/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 44)	0.1 (± 2.1)	-0.4 (± 2.4)	-0.5 (± 2.4)	-0.5 (± 1.9)
Week 4 (44, 44, 43, 46)	-0.5 (± 2.4)	-0.4 (± 2.3)	-0.2 (± 2.4)	-0.3 (± 1.9)
Week 8 (44, 43, 44, 44)	-0.3 (± 2.3)	-0.3 (± 2.5)	-0.3 (± 3.0)	0.1 (± 2.2)
Week 12 (44, 44, 45, 44)	-0.1 (± 2.2)	0.2 (± 2.7)	0.2 (± 2.7)	0.7 (± 3.0)

Week 16 (44, 45, 43, 45)	0.0 (± 2.5)	1.0 (± 2.5)	0.1 (± 2.9)	-0.2 (± 2.9)
Week 20 (43, 45, 42, 44)	-0.7 (± 2.7)	0.1 (± 2.7)	0.4 (± 2.4)	0.4 (± 2.2)
Week 24 (42, 43, 44, 44)	-0.1 (± 2.9)	0.0 (± 2.1)	0.4 (± 2.4)	1.2 (± 2.7)
Week 28 (43, 43, 40, 43)	-0.7 (± 3.0)	-0.4 (± 2.3)	0.1 (± 2.9)	0.1 (± 2.6)
Week 32 (44, 44, 43, 45)	0.6 (± 2.8)	-0.1 (± 3.0)	0.9 (± 3.2)	0.7 (± 2.8)
Week 40 (42, 42, 41, 44)	0.1 (± 2.8)	-0.1 (± 2.9)	0.2 (± 2.6)	0.3 (± 3.0)
Week 48 (38, 42, 40, 43)	0.1 (± 2.8)	-0.7 (± 3.0)	0.2 (± 3.0)	-0.8 (± 3.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Glucose

End point title	Mean change from baseline in Glucose

End point description:

Glucose was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 44, 43)	0.18 (± 0.75)	0.26 (± 0.70)	0.09 (± 0.78)	0.13 (± 1.28)
Week 4 (44, 44, 43, 46)	0.04 (± 0.71)	0.03 (± 0.70)	-0.04 (± 0.90)	0.11 (± 1.10)
Week 8 (44, 43, 44, 44)	0.17 (± 0.66)	0.12 (± 0.90)	0.23 (± 0.95)	0.12 (± 1.16)
Week 12 (44, 44, 43, 44)	-0.08 (± 0.69)	0.08 (± 0.66)	-0.13 (± 0.79)	-0.15 (± 0.99)
Week 16 (44, 45, 43, 45)	0.11 (± 0.77)	0.06 (± 0.63)	0.16 (± 0.92)	-0.18 (± 1.47)
Week 20 (43, 44, 42, 43)	0.16 (± 0.85)	0.20 (± 0.84)	0.13 (± 0.83)	-0.08 (± 1.01)
Week 24 (42, 43, 43, 43)	-0.07 (± 0.85)	0.05 (± 0.49)	-0.09 (± 0.73)	-0.22 (± 1.06)
Week 28 (39, 43, 40, 43)	0.22 (± 1.01)	0.09 (± 0.76)	-0.01 (± 0.74)	0.07 (± 1.22)
Week 32 (44, 44, 42, 45)	-0.04 (± 0.72)	-0.07 (± 0.63)	-0.08 (± 0.65)	0.06 (± 1.10)
Week 40 (41, 41, 41, 44)	-0.05 (± 0.62)	0.08 (± 0.71)	-0.09 (± 0.68)	-0.08 (± 1.07)
Week 48 (38, 42, 40, 43)	-0.14 (± 0.78)	-0.11 (± 0.61)	-0.06 (± 0.64)	-0.14 (± 1.25)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Lipase, Pancreatic

End point title	Mean change from baseline in Lipase, Pancreatic

End point description:

Lipase, Pancreatic was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: U/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 44)	-1.1 (± 10.5)	2.2 (± 11.9)	0.1 (± 9.2)	-0.2 (± 7.5)
Week 4 (44, 44, 43, 46)	-2.1 (± 9.8)	0.9 (± 9.1)	0.1 (± 10.6)	-1.2 (± 10.0)
Week 8 (44, 43, 44, 44)	-3.1 (± 9.2)	3.7 (± 11.8)	2.0 (± 20.0)	-1.8 (± 10.3)
Week 12 (44, 44, 45, 44)	-0.5 (± 8.7)	1.0 (± 11.1)	-0.7 (± 13.4)	-0.6 (± 9.6)
Week 16 (44, 45, 43, 45)	0.4 (± 7.4)	2.7 (± 8.4)	0.5 (± 11.3)	-0.2 (± 11.8)
Week 20 (43, 45, 42, 44)	-0.6 (± 10.4)	2.1 (± 8.0)	-0.9 (± 9.0)	-1.7 (± 9.3)
Week 24 (42, 43, 44, 44)	-0.5 (± 11.0)	-0.1 (± 9.1)	-0.1 (± 8.1)	1.2 (± 11.8)
Week 28 (43, 43, 40, 43)	1.6 (± 13.1)	1.7 (± 10.5)	0.5 (± 11.9)	1.7 (± 14.1)
Week 32 (44, 44, 43, 45)	1.1 (± 15.1)	1.0 (± 11.0)	1.2 (± 10.6)	3.8 (± 21.6)
Week 40 (42, 42, 41, 44)	1.2 (± 11.0)	1.3 (± 7.0)	-0.3 (± 8.9)	2.5 (± 8.9)
Week 48 (38, 42, 40, 43)	1.4 (± 10.1)	2.2 (± 10.0)	0.3 (± 10.7)	3.7 (± 10.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Creatine Kinase

End point title	Mean change from baseline in Creatine Kinase

End point description:

Creatine Kinase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: U/L				
arithmetic mean (standard deviation)				
Week 2 (42, 45, 45, 43)	-3.0 (± 67.1)	-2.2 (± 55.6)	-2.2 (± 18.2)	0.1 (± 46.5)
Week 4 (44, 44, 43, 46)	29.6 (± 218.4)	-6.2 (± 54.8)	3.2 (± 22.0)	-16.9 (± 56.5)
Week 8 (44, 43, 44, 44)	-4.9 (± 56.9)	-8.5 (± 52.7)	-1.5 (± 23.6)	-4.6 (± 122.1)
Week 12 (44, 44, 45, 44)	-6.3 (± 57.5)	-8.4 (± 85.8)	-3.0 (± 22.4)	-29.4 (± 80.7)
Week 16 (44, 45, 43, 45)	0.9 (± 59.4)	-11.5 (± 105.1)	-7.5 (± 22.2)	-23.2 (± 106.3)
Week 20 (43, 43, 42, 44)	-8.2 (± 60.0)	5.9 (± 149.1)	-3.5 (± 22.2)	-33.4 (± 95.3)
Week 24 (42, 43, 44, 44)	-6.4 (± 48.6)	-5.4 (± 123.7)	-2.6 (± 27.4)	-27.7 (± 98.9)
Week 28 (43, 42, 40, 43)	-1.5 (± 67.3)	-19.1 (± 131.5)	-0.7 (± 25.4)	-36.7 (± 103.8)
Week 32 (44, 44, 43, 45)	2.0 (± 67.0)	-10.0 (± 167.0)	34.0 (± 222.1)	-24.2 (± 91.2)
Week 40 (42, 42, 41, 44)	9.9 (± 109.1)	-20.4 (± 131.4)	-2.7 (± 25.4)	-16.3 (± 106.4)
Week 48 (38, 42, 40, 43)	7.8 (± 67.3)	-20.4 (± 138.3)	-3.6 (± 25.5)	-33.4 (± 106.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in pH

End point title	Mean change from baseline in pH

End point description:

The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: pH				
arithmetic mean (standard deviation)				
Week 2 (43, 43, 44, 43)	-0.01 (± 0.66)	0.03 (± 0.62)	-0.07 (± 0.67)	0.15 (± 0.78)
Week 4 (43, 43, 43, 43)	0.10 (± 0.77)	0.15 (± 0.52)	0.06 (± 0.72)	0.16 (± 0.74)
Week 8 (42, 44, 44, 42)	-0.12 (± 0.79)	0.00 (± 0.62)	-0.08 (± 0.56)	-0.04 (± 0.65)
Week 12 (44, 43, 43, 42)	0.00 (± 0.81)	0.15 (± 0.69)	0.03 (± 0.79)	0.20 (± 0.83)
Week 16 (44, 45, 39, 45)	-0.02 (± 0.61)	0.00 (± 0.51)	-0.09 (± 0.81)	0.11 (± 0.69)

Week 20 (42, 43, 41, 43)	-0.11 (± 0.75)	-0.01 (± 0.59)	0.06 (± 0.58)	0.07 (± 0.88)
Week 24 (43, 42, 44, 42)	0.03 (± 0.85)	-0.01 (± 0.46)	-0.11 (± 0.81)	0.02 (± 0.81)
Week 28 (44, 42, 42, 41)	-0.13 (± 0.84)	-0.06 (± 0.57)	-0.05 (± 0.73)	-0.01 (± 0.69)
Week 32 (44, 44, 42, 43)	-0.02 (± 0.75)	-0.03 (± 0.55)	-0.18 (± 0.66)	0.09 (± 0.86)
Week 40 (42, 43, 41, 44)	-0.14 (± 0.81)	0.19 (± 0.66)	-0.21 (± 0.81)	-0.07 (± 0.62)
Week 48 (38, 42, 40, 43)	-0.11 (± 0.66)	0.06 (± 0.73)	-0.11 (± 0.74)	-0.08 (± 0.72)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Erythrocytes (/HPF)

End point title	Mean change from baseline in Erythrocytes (/HPF)

End point description:

The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: % of Erythrocytes per HPF				
arithmetic mean (standard deviation)				
Week 2 (43, 43, 44, 43)	-6.8 (± 53.7)	0.1 (± 8.4)	0.2 (± 2.4)	0.9 (± 7.9)
Week 4 (43, 43, 43, 43)	-8.7 (± 52.6)	-0.8 (± 4.1)	1.4 (± 10.5)	-0.6 (± 3.2)
Week 8 (42, 44, 44, 42)	-8.7 (± 53.5)	-0.3 (± 6.9)	0.4 (± 6.1)	0.0 (± 6.8)
Week 12 (44, 43, 43, 42)	-8.6 (± 52.6)	1.3 (± 17.4)	-0.4 (± 2.4)	17.4 (± 118.5)
Week 16 (43, 45, 39, 45)	-5.7 (± 48.0)	-1.3 (± 4.1)	-0.6 (± 2.6)	-0.5 (± 5.5)
Week 20 (42, 43, 41, 43)	-7.7 (± 53.7)	-1.0 (± 3.5)	-0.1 (± 3.9)	-0.6 (± 4.4)
Week 24 (43, 42, 44, 42)	-7.2 (± 53.5)	-1.2 (± 3.9)	-0.3 (± 2.3)	-0.9 (± 4.6)
Week 28 (44, 42, 42, 41)	-7.6 (± 51.3)	-1.3 (± 4.2)	-0.7 (± 2.9)	3.0 (± 16.9)
Week 32 (44, 44, 42, 43)	-8.5 (± 52.5)	4.9 (± 41.8)	0.0 (± 3.9)	0.1 (± 4.5)
Week 40 (42, 43, 41, 44)	-9.1 (± 53.2)	3.5 (± 18.8)	-0.5 (± 3.5)	0.4 (± 5.4)
Week 48 (38, 42, 40, 43)	-9.7 (± 56.3)	-0.4 (± 5.4)	1.9 (± 15.5)	0.1 (± 4.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Leukocytes (/HPF)

End point title	Mean change from baseline in Leukocytes (/HPF)

End point description:

The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

From Baseline (Week 1) to Week 48

End point values	SOC + Placebo iv Q4W (SS)	SOC + DZP 6mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	45	45	47
Units: % of Leukocytes per HPF				
arithmetic mean (standard deviation)				
Week 2 (43, 43, 44, 43)	-0.1 (± 11.4)	-1.4 (± 8.1)	-0.8 (± 2.9)	2.9 (± 13.7)
Week 4 (43, 43, 43, 43)	-0.2 (± 9.0)	-0.6 (± 8.5)	-0.7 (± 4.5)	3.0 (± 12.6)
Week 8 (42, 44, 44, 42)	-1.2 (± 10.4)	4.8 (± 29.3)	-0.3 (± 6.8)	3.0 (± 14.4)
Week 12 (44, 43, 43, 42)	-1.1 (± 11.3)	4.4 (± 42.2)	-1.3 (± 4.2)	2.7 (± 13.9)
Week 16 (43, 45, 39, 45)	0.1 (± 9.6)	-1.6 (± 12.5)	-0.2 (± 9.6)	1.8 (± 12.9)
Week 20 (42, 43, 41, 43)	-0.1 (± 10.1)	3.7 (± 13.3)	0.4 (± 9.8)	1.7 (± 4.0)
Week 24 (43, 42, 44, 42)	-1.0 (± 10.9)	10.7 (± 52.1)	-0.7 (± 4.5)	0.4 (± 4.5)
Week 28 (44, 42, 42, 41)	-0.2 (± 9.6)	2.4 (± 9.7)	-1.1 (± 4.4)	2.0 (± 10.1)
Week 32 (44, 44, 42, 43)	-0.6 (± 10.8)	-0.5 (± 13.5)	-1.0 (± 5.4)	4.1 (± 15.7)
Week 40 (42, 43, 41, 44)	-1.6 (± 10.4)	2.2 (± 19.8)	1.4 (± 7.7)	6.8 (± 30.9)
Week 48 (38, 42, 40, 43)	-0.3 (± 8.9)	10.8 (± 71.9)	-1.0 (± 4.0)	0.8 (± 5.3)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from Baseline (Week 1) until end of the study (Week 48)

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups

Reporting group title	SOC + Placebo iv Q4W (SS)

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the Safety Set (SS).

Reporting group title	SOC + DZP 45mg/kg iv Q4W (SS)

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the SS.

Reporting group title	SOC + DZP 24mg/kg iv Q4W (SS)

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the SS.

Reporting group title	SOC + DZP 6mg/kg iv Q4W (SS)

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the SS.

Serious adverse events	SOC + Placebo iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 45 (13.33%)	5 / 47 (10.64%)	6 / 45 (13.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thoracic vertebral fracture			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (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			

Deep vein thrombosis			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (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
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (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 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Antiphospholipid syndrome			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (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
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (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
Haemorrhagic disorder			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (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
Gastrointestinal disorders			
Anastomotic ulcer perforation			

subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (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
Respiratory, thoracic and mediastinal disorders			
Pneumothorax			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (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			
Lupus nephritis			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (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
Nephrosclerosis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (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 tubular necrosis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (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			
Systemic lupus erythematosus			
subjects affected / exposed	1 / 45 (2.22%)	1 / 47 (2.13%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			

subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	0 / 45 (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
Influenza			
subjects affected / exposed	1 / 45 (2.22%)	0 / 47 (0.00%)	0 / 45 (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
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (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
Urinary tract infection			
subjects affected / exposed	0 / 45 (0.00%)	1 / 47 (2.13%)	0 / 45 (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
Appendicitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 47 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	SOC + DZP 6mg/kg iv Q4W (SS)		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 45 (11.11%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Injury, poisoning and procedural complications			
Thoracic vertebral fracture			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Antiphospholipid syndrome			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Autoimmune haemolytic anaemia			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic disorder			

subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Anastomotic ulcer perforation			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pneumothorax			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Lupus nephritis			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrosclerosis			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal tubular necrosis			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Systemic lupus erythematosus			

subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	SOC + Placebo iv Q4W (SS)	SOC + DZP 45mg/kg iv Q4W (SS)	SOC + DZP 24mg/kg iv Q4W (SS)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 45 (48.89%)	25 / 47 (53.19%)	24 / 45 (53.33%)
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	3 / 45 (6.67%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	3	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 45 (2.22%)	2 / 47 (4.26%)	3 / 45 (6.67%)
occurrences (all)	1	2	4
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 45 (13.33%)	3 / 47 (6.38%)	4 / 45 (8.89%)
occurrences (all)	6	3	6
Migraine			
subjects affected / exposed	0 / 45 (0.00%)	3 / 47 (6.38%)	1 / 45 (2.22%)
occurrences (all)	0	3	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 45 (6.67%)	3 / 47 (6.38%)	4 / 45 (8.89%)
occurrences (all)	3	3	4
Nausea			
subjects affected / exposed	2 / 45 (4.44%)	2 / 47 (4.26%)	3 / 45 (6.67%)
occurrences (all)	2	2	3
Dyspepsia			
subjects affected / exposed	5 / 45 (11.11%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	5	0	0
Abdominal pain upper			
subjects affected / exposed	3 / 45 (6.67%)	0 / 47 (0.00%)	0 / 45 (0.00%)
occurrences (all)	3	0	0
Psychiatric disorders			
Anxiety			

subjects affected / exposed	2 / 45 (4.44%)	0 / 47 (0.00%)	3 / 45 (6.67%)
occurrences (all)	2	0	3
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 45 (4.44%)	2 / 47 (4.26%)	0 / 45 (0.00%)
occurrences (all)	3	2	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 45 (4.44%)	5 / 47 (10.64%)	6 / 45 (13.33%)
occurrences (all)	2	5	7
Upper respiratory tract infection			
subjects affected / exposed	4 / 45 (8.89%)	7 / 47 (14.89%)	3 / 45 (6.67%)
occurrences (all)	5	9	5
Pharyngitis			
subjects affected / exposed	3 / 45 (6.67%)	5 / 47 (10.64%)	4 / 45 (8.89%)
occurrences (all)	3	6	6
Urinary tract infection			
subjects affected / exposed	2 / 45 (4.44%)	2 / 47 (4.26%)	4 / 45 (8.89%)
occurrences (all)	3	2	4
Bronchitis			
subjects affected / exposed	0 / 45 (0.00%)	3 / 47 (6.38%)	2 / 45 (4.44%)
occurrences (all)	0	3	2
Influenza			
subjects affected / exposed	1 / 45 (2.22%)	3 / 47 (6.38%)	3 / 45 (6.67%)
occurrences (all)	1	3	3

Non-serious adverse events	SOC + DZP 6mg/kg iv Q4W (SS)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 45 (57.78%)		
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hypertension			

subjects affected / exposed occurrences (all)	3 / 45 (6.67%) 3		
Nervous system disorders Headache subjects affected / exposed occurrences (all) Migraine subjects affected / exposed occurrences (all)	 6 / 45 (13.33%) 14 0 / 45 (0.00%) 0		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Dyspepsia subjects affected / exposed occurrences (all) Abdominal pain upper subjects affected / exposed occurrences (all)	 4 / 45 (8.89%) 4 1 / 45 (2.22%) 1 1 / 45 (2.22%) 2 0 / 45 (0.00%) 0		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	 1 / 45 (2.22%) 1		
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	 5 / 45 (11.11%) 6		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection	 5 / 45 (11.11%) 7 		

subjects affected / exposed	5 / 45 (11.11%)		
occurrences (all)	5		
Pharyngitis			
subjects affected / exposed	4 / 45 (8.89%)		
occurrences (all)	5		
Urinary tract infection			
subjects affected / exposed	7 / 45 (15.56%)		
occurrences (all)	7		
Bronchitis			
subjects affected / exposed	3 / 45 (6.67%)		
occurrences (all)	5		
Influenza			
subjects affected / exposed	3 / 45 (6.67%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported