



Clinical trial results:

A Randomized, Placebo-controlled Double-blind, Multicenter, Phase 2 Dose Ranging Study To Assess The Efficacy And Safety of CNTO6785 In Subjects With Active Rheumatoid Arthritis Despite Methotrexate Therapy.

Summary

EudraCT number	2012-003629-40
Trial protocol	CZ
Global end of trial date	26 May 2015

Results information

Result version number	v1 (current)
This version publication date	25 May 2016
First version publication date	25 May 2016

Trial information

Trial identification

Sponsor protocol code	CNTO6785ARA2001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01909427
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janseen-Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, BEERSE, Belgium, 2340
Public contact	Clinical Registry Group, Janseen-Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janseen-Cilag International NV, ClinicalTrialsEU@its.jnj.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	26 May 2015
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	26 May 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to assess the efficacy of CNT06785 on the signs and symptoms in subjects with active Rheumatoid Arthritis (RA) compared with Placebo despite concomitant Methotrexate (MTX) Therapy

Protection of trial subjects:

To protect the subjects in the study, a series of risk management actions were considered, excluding subjects with potential risks entering into the study, designed the discontinuation criteria during the study, applying for the comprehensive medical monitoring of clinical data on an ongoing basis and an internal Data Reviewing Committee to review unblinded data during the study ongoing. Safety monitoring also include assessing Adverse Events, brief physical examinations, vital signs measurements, electrocardiogram (ECG) measurements, signs and symptoms of active tuberculosis (TB), laboratory assessments including chemistry, hematology and urinalysis during the study.

Background therapy:

Methotrexate

Evidence for comparator:

Placebo

Actual start date of recruitment	09 May 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 47
Country: Number of subjects enrolled	Colombia: 23
Country: Number of subjects enrolled	Czech Republic: 18
Country: Number of subjects enrolled	Philippines: 20
Country: Number of subjects enrolled	Poland: 62
Country: Number of subjects enrolled	Russian Federation: 73
Country: Number of subjects enrolled	Thailand: 14
Worldwide total number of subjects	257
EEA total number of subjects	80

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)	228
From 65 to 84 years	29
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 257 male and female subjects with active Rheumatoid Arthritis (RA) despite Methotrexate (MTX) therapy were enrolled in the study.

Pre-assignment

Screening details:

This study consist of Screening phase from Week -6 to Week 0 followed by treatment phase from Week 0 to Week 28, and follow up phase from Week 28 to Week 38.

Period 1

Period 1 title	Double Blind Treatment Phase (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received Placebo as Subcutaneous injection (SC) at Week 0, 4, 8 and 12. From Week 16, subjects started to receive 200 mg of CNTO6785 SC every 4 weeks through week 28 named as Placebo-CNTO6785 200 mg group thereafter in this report.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects administered with Placebo subcutaneous injections (SC) every 4 weeks through Week 12. From Week 16, subjects started receiving CNTO6785 200 mg SC every 4 weeks through Week 28, also named the arm title as Placebo-CNTO6785 200 mg.

Arm title	CNTO6785, 15 mg
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Arm description:

Subjects received 15 mg of CNTO6785 as SC every 4 weeks through Week 28.

Arm type	Experimental
Investigational medicinal product name	CNTO6785 15 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects administered with CNTO6785 15 mg SC every 4 weeks through Week 28.

Arm title	CNTO6785, 50 mg
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Arm description:

Subjects received 50 mg of CNTO6785 as SC every 4 weeks through Week 28.

Arm type	Experimental
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Investigational medicinal product name	CNTO6785 50 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Subjects administered with CNTO6785 50 mg SC every 4 weeks through Week 28.	
Arm title	CNTO6785,100mg

Arm description:

Subjects received 100 mg of CNTO6785 as SC every 4 weeks through Week 28.

Arm type	Experimental
Investigational medicinal product name	CNTO6785 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects administered with CNTO6785 100 mg SC every 4 weeks through Week 28.

Arm title	CNTO6785, 200mg
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Arm description:

Subjects received 200 mg of CNTO6785 as SC every 4 weeks through Week 28.

Arm type	Experimental
Investigational medicinal product name	CNTO6785 200mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects administered with CNTO 6785 200 mg SC every 4 weeks through Week 28.

Number of subjects in period 1	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg
Started	51	52	51
Completed	48	50	48
Not completed	3	2	3
Consent withdrawn by subject	1	-	1
Physician decision	-	1	1
Adverse event, non-fatal	-	1	1
Other	2	-	-

Number of subjects in period 1	CNTO6785,100mg	CNTO6785, 200mg
Started	51	52
Completed	48	48
Not completed	3	4
Consent withdrawn by subject	-	2
Physician decision	1	1

Adverse event, non-fatal	1	1
Other	1	-

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received Placebo as Subcutaneous injection (SC) at Week 0, 4, 8 and 12. From Week 16, subjects started to receive 200 mg of CNTO6785 SC every 4 weeks through week 28 named as Placebo-CNTO6785 200 mg group thereafter in this report.	
Reporting group title	CNTO6785, 15 mg
Reporting group description: Subjects received 15 mg of CNTO6785 as SC every 4 weeks through Week 28.	
Reporting group title	CNTO6785, 50 mg
Reporting group description: Subjects received 50 mg of CNTO6785 as SC every 4 weeks through Week 28.	
Reporting group title	CNTO6785,100mg
Reporting group description: Subjects received 100 mg of CNTO6785 as SC every 4 weeks through Week 28.	
Reporting group title	CNTO6785, 200mg
Reporting group description: Subjects received 200 mg of CNTO6785 as SC every 4 weeks through Week 28.	

Reporting group values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg
Number of subjects	51	52	51
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	48	44	44
From 65 to 84 years	3	8	7
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	49.8	49.5	52.3
standard deviation	± 11.63	± 14.33	± 10.83
Title for Gender Units: subjects			
Female	45	40	45
Male	6	12	6

Reporting group values	CNTO6785,100mg	CNTO6785, 200mg	Total
Number of subjects	51	52	257
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	46	46	228
From 65 to 84 years	5	6	29
85 years and over	0	0	0

Title for AgeContinuous Units: years arithmetic mean standard deviation	52.3 ± 11.91	52.9 ± 9.68	-
Title for Gender Units: subjects			
Female	46	40	216
Male	5	12	41

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received Placebo as Subcutaneous injection (SC) at Week 0, 4, 8 and 12. From Week 16, subjects started to receive 200 mg of CNTO6785 SC every 4 weeks through week 28 named as Placebo-CNTO6785 200 mg group thereafter in this report.	
Reporting group title	CNTO6785, 15 mg
Reporting group description: Subjects received 15 mg of CNTO6785 as SC every 4 weeks through Week 28.	
Reporting group title	CNTO6785, 50 mg
Reporting group description: Subjects received 50 mg of CNTO6785 as SC every 4 weeks through Week 28.	
Reporting group title	CNTO6785,100mg
Reporting group description: Subjects received 100 mg of CNTO6785 as SC every 4 weeks through Week 28.	
Reporting group title	CNTO6785, 200mg
Reporting group description: Subjects received 200 mg of CNTO6785 as SC every 4 weeks through Week 28.	
Subject analysis set title	Placebo-CNTO6785 200mg
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: Subjects received placebo through Week 12 and then switched to receive CNTO6785 200 mg from Week 16 and every 4 weeks thereafter up to Week 28 .	

Primary: Percentage of Subjects who Achieved an American College of Rheumatology (ACR 20) Response at Week 16

End point title	Percentage of Subjects who Achieved an American College of Rheumatology (ACR 20) Response at Week 16
End point description: The ACR 20 response is a greater than or equal to ($\geq$) 20 percentage improvement in rheumatoid arthritis (RA) signs and symptoms. Modified intent to treat (mITT) analysis set included all subjects who received at least a partial dose of the study drug.	
End point type	Primary
End point timeframe: Week 16	

End point values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: Percentage of subjects				
number (not applicable)	41.2	51.9	47.1	37.3

End point values	CNTO6785, 200mg			
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Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Percentage of subjects				
number (not applicable)	40.4			

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v CNTO6785, 15 mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2718
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v CNTO6785, 50 mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5629
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v CNTO6785,100mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6862
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo v CNTO6785, 200mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9516
Method	Cochran-Mantel-Haenszel

Secondary: Change From Baseline in Disease Activity Score 28 (DAS 28 [C-reactive protein {CRP}]) at Week 16

End point title	Change From Baseline in Disease Activity Score 28 (DAS 28 [C-reactive protein {CRP}]) at Week 16
End point description: The DAS28 based on CRP is a statistically derived index combining tender joints (28 joints), swollen joints (28 joints), CRP and subjects global assessment of disease activity. mITT analysis set included all subjects who received at least a partial dose of the study drug.	
End point type	Secondary
End point timeframe: Week 16	

End point values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: units on scale				
least squares mean (standard error)	-1.3255 (± 0.17361)	-1.7519 (± 0.17215)	-1.7176 (± 0.17422)	-1.5836 (± 0.17352)

End point values	CNTO6785, 200mg			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: units on scale				
least squares mean (standard error)	-1.4565 (± 0.17349)			

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v CNTO6785, 15 mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0748
Method	ANCOVA
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.0356
upper limit	-1.4681

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v CNTO6785, 50 mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.103
Method	ANCOVA
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.0047
upper limit	-1.4304

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v CNTO6785,100mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2825
Method	ANCOVA
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.8696
upper limit	-1.2976

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo v CNTO6785, 200mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5853
Method	ANCOVA
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.7425
upper limit	-1.1706

Secondary: Percentage of Subjects who Achieved ACR 50 Response at Week 16	
End point title	Percentage of Subjects who Achieved ACR 50 Response at Week 16

End point description:

The ACR 50 response is a $\geq 50\%$ improvement in RA signs and symptoms. mITT analysis set included

all subjects who received at least a partial dose of the study drug.

End point type	Secondary
End point timeframe:	
Week 16	

End point values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: Percentage of subjects				
number (not applicable)	19.6	25	19.6	11.8

End point values	CNTO6785, 200mg			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Percentage of subjects				
number (not applicable)	17.3			

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v CNTO6785, 15 mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5003
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v CNTO6785, 50 mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9763
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v CNTO6785,100mg

Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2721
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo v CNTO6785, 200mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7721
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Subjects who Achieved ACR 20 Response Through Week 32

End point title	Percentage of Subjects who Achieved ACR 20 Response Through Week 32
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End point description:

The ACR 20 response is a $\geq 20\%$ improvement in RA signs and symptoms. mITT analysis set included all subjects who received at least a partial dose of the study drug. Here, 99999 signifies that no subjects were in Placebo group after Week 16 and in Placebo-CNTO6785 200 mg group till Week 16.

End point type	Secondary
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End point timeframe:

Up to Week 32

End point values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785, 100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: Percentage of subjects				
number (not applicable)				
Week 2	19.6	21.2	35.3	25.5
Week 4	35.3	17.3	35.3	31.4
Week 8	35.3	34.6	41.2	45.1
Week 12	43.1	44.2	52.9	35.3
Week 16	41.2	51.9	47.1	37.3
Week 20	99999	50	47.1	33.3
Week 24	99999	48.1	37.3	45.1
Week 28	99999	46.2	60.8	37.3
Week 32	99999	46.2	56.9	47.1

End point values	CNTO6785, 200mg	Placebo- CNTO6785 200mg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	51		
Units: Percentage of subjects				
number (not applicable)				
Week 2	30.8	99999		
Week 4	28.8	99999		
Week 8	30.8	99999		
Week 12	42.3	99999		
Week 16	40.4	99999		
Week 20	46.2	51		
Week 24	48.1	64.7		
Week 28	50	64.7		
Week 32	57.7	54.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ACR 50 Response Through Week 32

End point title	Percentage of Subjects who Achieved ACR 50 Response Through Week 32
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End point description:

The ACR 50 response is a $\geq 50\%$ improvement in RA signs and symptoms. mITT analysis set included all subjects who received at least a partial dose of the study drug. Here, 99999 signifies that no subjects were in Placebo group after Week 16 and in Placebo-CNTO6785 200 mg group till Week 16.

End point type	Secondary
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End point timeframe:

Up to Week 32

End point values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: Percentage of subjects				
number (not applicable)				
Week 2	0	1.9	2	3.9
Week 4	7.8	7.7	5.9	7.8
Week 8	11.8	7.7	9.8	13.7
Week 12	13.7	21.2	11.8	11.8
Week 16	19.6	25	19.6	11.8
Week 20	99999	25	29.4	7.8
Week 24	99999	28.8	23.5	7.8
Week 28	99999	23.1	29.4	15.7
Week 32	99999	34.6	31.4	19.6

End point values	CNT06785, 200mg	Placebo- CNT06785 200mg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	51		
Units: Percentage of subjects				
number (not applicable)				
Week 2	5.8	99999		
Week 4	3.8	99999		
Week 8	13.5	99999		
Week 12	15.4	99999		
Week 16	17.3	99999		
Week 20	19.2	37.3		
Week 24	25	29.4		
Week 28	25	39.2		
Week 32	30.8	37.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ACR 70 Response Through Week 32

End point title	Percentage of Subjects who Achieved ACR 70 Response Through Week 32
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End point description:

ACR 70 response is a $\geq 70\%$ improvement in RA signs and symptoms. mITT analysis set included all subjects who received at least a partial dose of the study drug. Here, 99999 signifies that no subjects were in Placebo group after Week 16 and in Placebo-CNT06785 200 mg group till Week 16.

End point type	Secondary
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End point timeframe:

Up to Week 32

End point values	Placebo	CNT06785, 15 mg	CNT06785, 50 mg	CNT06785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: Percentage of subjects				
number (not applicable)				
Week 2	0	0	0	0
Week 4	2	1.9	0	2
Week 8	2	0	0	5.9
Week 12	3.9	5.8	2	2
Week 16	7.8	9.6	9.8	5.9
Week 20	99999	11.5	11.8	3.9

Week 24	99999	15.4	15.7	3.9
Week 28	99999	13.5	21.6	5.9
Week 32	99999	23.1	23.5	11.8

End point values	CNT06785, 200mg	Placebo- CNT06785 200mg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	51		
Units: Percentage of subjects				
number (not applicable)				
Week 2	0	99999		
Week 4	0	99999		
Week 8	0	99999		
Week 12	3.8	99999		
Week 16	1.9	99999		
Week 20	9.6	13.7		
Week 24	11.5	19.6		
Week 28	9.6	17.6		
Week 32	15.4	17.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in DAS28 (CRP) Through Week 32

End point title	Change From Baseline in DAS28 (CRP) Through Week 32
End point description:	
The DAS28 based on CRP is a statistically derived index combining tender joints (28 joints), swollen joints (28 joints), CRP and subjects global assessment of disease activity. mITT analysis set included all subjects who received at least a partial dose of the study drug. Here, 99999 signifies that no subjects were in Placebo group after Week 16 and in Placebo-CNT06785 200 mg group till Week 16. Here, 'n' signifies number of subjects analyzed for this endpoint at given timepoint.	
End point type	Secondary
End point timeframe:	
Baseline up to Week 32	

End point values	Placebo	CNT06785, 15 mg	CNT06785, 50 mg	CNT06785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: units on scale				
least squares mean (standard error)				
Change at Week 2 (n= 51, 51, 51, 50, 51, 0)	-0.5833 (± 0.11967)	-0.8358 (± 0.12017)	-0.8834 (± 0.1201)	-0.7587 (± 0.12063)

Change at Week 4 (n= 51, 52, 51, 50, 51, 0)	-0.7356 (± 0.13715)	-0.8687 (± 0.136)	-0.9805 (± 0.13763)	-0.9781 (± 0.13826)
Change at Week 8 (n= 51, 52, 51, 51, 51, 0)	-0.9657 (± 0.14857)	-1.229 (± 0.14733)	-1.303 (± 0.14909)	-1.3166 (± 0.14849)
Change at Week 12 (n= 51, 52, 51, 51, 51, 0)	-1.2594 (± 0.16009)	-1.3984 (± 0.15874)	-1.5975 (± 0.16065)	-1.321 (± 0.16)
Change at Week 16 (n= 51, 52, 51, 51, 51, 0)	-1.3255 (± 0.17361)	-1.7519 (± 0.17215)	-1.7176 (± 0.17422)	-1.5836 (± 0.17352)
Change at Week 20 (n= 0, 52, 51, 51, 51, 51)	99999 (± 99999)	-1.7754 (± 0.17468)	-1.8309 (± 0.17674)	-1.4073 (± 0.1761)
Change at Week 24 (n= 0, 52, 51, 51, 51, 51)	99999 (± 99999)	-1.835 (± 0.18912)	-1.8298 (± 0.19135)	-1.6945 (± 0.19066)
Change at Week 28 (n= 0, 52, 51, 51, 51, 51)	99999 (± 99999)	-1.7537 (± 0.18084)	-2.1819 (± 0.18298)	-1.8096 (± 0.18232)
Change at Week 32 (n= 0, 52, 51, 51, 51, 51)	99999 (± 99999)	-1.9354 (± 0.1887)	-2.2117 (± 0.19093)	-2.0158 (± 0.19023)

End point values	CNT06785, 200mg	Placebo- CNT06785 200mg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	51		
Units: units on scale				
least squares mean (standard error)				
Change at Week 2 (n= 51, 51, 51, 50, 51, 0)	-0.8708 (± 0.11958)	99999 (± 99999)		
Change at Week 4 (n= 51, 52, 51, 50, 51, 0)	-0.9602 (± 0.13705)	99999 (± 99999)		
Change at Week 8 (n= 51, 52, 51, 51, 51, 0)	-1.0021 (± 0.14847)	99999 (± 99999)		
Change at Week 12 (n= 51, 52, 51, 51, 51, 0)	-1.3586 (± 0.15998)	99999 (± 99999)		
Change at Week 16 (n= 51, 52, 51, 51, 51, 0)	-1.4565 (± 0.17349)	99999 (± 99999)		
Change at Week 20 (n= 0, 52, 51, 51, 51, 51)	-1.5692 (± 0.17608)	-1.8127 (± 0.17618)		
Change at Week 24 (n= 0, 52, 51, 51, 51, 51)	-1.6848 (± 0.19063)	-2.0472 (± 0.19074)		
Change at Week 28 (n= 0, 52, 51, 51, 51, 51)	-1.8364 (± 0.18229)	-2.1183 (± 0.1824)		
Change at Week 32 (n= 0, 52, 51, 51, 51, 51)	-2.0259 (± 0.19021)	-2.2459 (± 0.19032)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With DAS28 (CRP) Response Through Week 32

End point title	Percentage of Subjects With DAS28 (CRP) Response Through Week 32
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End point description:

The DAS28 (using CRP) response is improvement from baseline, with >1.2 indicating a good or moderate response, and between 0.6 and 1.2 inclusive indicating moderate response if DAS28 at the visit is ≤5.1 or no response if DAS28 at the visit is >5.1 and ≤0.6 indicating no response. mITT

analysis set included all subjects who received at least a partial dose of the study drug. Here, 99999 signifies that no subjects were in Placebo group after Week 16 and in Placebo-CNTO6785 200 mg group till Week 16. Here, 'n' signifies number of subjects analyzed for this endpoint at given timepoint.

End point type	Secondary
End point timeframe:	
Up to Week 32	

End point values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: Percentage of subjects				
number (not applicable)				
Week 2 (n= 51, 51, 51, 50, 51, 0)	31.4	44.2	39.2	35.3
Week 4 (n= 51, 52, 51, 50, 51, 0)	43.1	42.3	45.1	56.9
Week 8 (n= 51, 52, 51, 51, 51, 0)	54.9	59.6	62.7	64.7
Week 12 (n= 51, 52, 51, 51, 51, 0)	62.7	65.4	72.5	60.8
Week 16 (n= 51, 52, 51, 51, 51, 0)	62.7	75	72.5	66.7
Week 20 (n= 0, 52, 51, 51, 51, 51)	99999	71.2	72.5	64.7
Week 24 (n= 0, 52, 51, 51, 51, 51)	99999	71.2	62.7	66.7
Week 28 (n= 0, 52, 51, 51, 51, 51)	99999	63.5	76.5	66.7
Week 32 (n= 0, 52, 51, 51, 51, 51)	99999	69.2	84.3	76.5

End point values	CNTO6785, 200mg	Placebo-CNTO6785 200mg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	51		
Units: Percentage of subjects				
number (not applicable)				
Week 2 (n= 51, 51, 51, 50, 51, 0)	32.7	99999		
Week 4 (n= 51, 52, 51, 50, 51, 0)	48.1	99999		
Week 8 (n= 51, 52, 51, 51, 51, 0)	51.9	99999		
Week 12 (n= 51, 52, 51, 51, 51, 0)	61.5	99999		
Week 16 (n= 51, 52, 51, 51, 51, 0)	53.8	99999		
Week 20 (n= 0, 52, 51, 51, 51, 51)	57.7	72.5		
Week 24 (n= 0, 52, 51, 51, 51, 51)	65.4	78.4		
Week 28 (n= 0, 52, 51, 51, 51, 51)	67.3	76.5		
Week 32 (n= 0, 52, 51, 51, 51, 51)	71.2	78.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With DAS28 (CRP) Remission at Week 16

End point title	Percentage of Subjects With DAS28 (CRP) Remission at Week 16
End point description: The DAS28 (using CRP) remission is defined as a value of <2.6 on the disease activity score, a measure of tender and swollen joints and the subjects assessment of disease activity. mITT analysis set included all subjects who received at least a partial dose of the study drug.	
End point type	Secondary
End point timeframe: Week 16	

End point values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: Percentage of subjects				
number (not applicable)	7.8	17.3	19.6	9.8

End point values	CNTO6785, 200mg			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Percentage of subjects				
number (not applicable)	13.5			

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v CNTO6785, 15 mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1502
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v CNTO6785, 50 mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0915
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v CNTO6785,100mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7304
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo v CNTO6785, 200mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3601
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Subjects With DAS28 (CRP) Remission at Week 32

End point title	Percentage of Subjects With DAS28 (CRP) Remission at Week 32 ^[1]
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End point description:

The DAS28 (using CRP) remission is defined as a value of less than (<) 2.6 on the disease activity score, a measure of tender and swollen joints and the subject's assessment of disease activity. mITT analysis set included all subjects who received at least a partial dose of the study drug.

End point type	Secondary
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End point timeframe:

Week 32

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data was reported for the specific arms.

End point values	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785,100 mg	CNTO6785, 200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	51	51	52
Units: Percentage of subjects				
number (not applicable)	19.2	19.6	19.6	23.1

End point values	Placebo- CNTO6785 200mg			
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Subject group type	Subject analysis set			
Number of subjects analysed	51			
Units: Percentage of subjects				
number (not applicable)	25.5			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in DAS28 (Erythrocyte sedimentation rate [ESR]) at Week 16

End point title	Change From Baseline in DAS28 (Erythrocyte sedimentation rate [ESR]) at Week 16
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End point description:

The DAS28 based on ESR is defined as a statistically derived index combining tender joints (28 joints), swollen joints (28 joints), ESR, and patient's global assessment of disease activity (GH). mITT analysis set included all subjects who received at least a partial dose of the study drug.

End point type	Secondary
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End point timeframe:

Week 16

End point values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: units on scale				
least squares mean (standard error)	-1.4717 ($\pm$ 0.18222)	-1.8829 ($\pm$ 0.18068)	-1.7996 ($\pm$ 0.18291)	-1.671 ($\pm$ 0.18214)

End point values	CNTO6785, 200mg			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: units on scale				
least squares mean (standard error)	-1.6757 ($\pm$ 0.18214)			

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v CNTO6785, 15 mg

Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1016
Method	ANCOVA

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v CNTO6785, 50 mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1937
Method	ANCOVA

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v CNTO6785,100mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4293
Method	ANCOVA

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo v CNTO6785, 200mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4187
Method	ANCOVA

Secondary: Change From Baseline in DAS28 (ESR) at Week 32

End point title	Change From Baseline in DAS28 (ESR) at Week 32 ^[2]
End point description: The DAS28 based on ESR is defined as a statistically derived index combining tender joints (28 joints), swollen joints (28 joints), ESR, and patient's global assessment of disease activity (GH). mITT analysis set included all subjects who received at least a partial dose of the study drug.	
End point type	Secondary
End point timeframe: Week 32	

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data was reported for the specific arms.

End point values	CNT06785, 15 mg	CNT06785, 50 mg	CNT06785,100 mg	CNT06785, 200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	51	51	51
Units: units on scale				
least squares mean (standard error)	-2.2022 ($\pm$ 0.19439)	-2.3277 ($\pm$ 0.19675)	-2.0893 ($\pm$ 0.196)	-2.2871 ($\pm$ 0.19602)

End point values	Placebo- CNT06785 200mg			
Subject group type	Subject analysis set			
Number of subjects analysed	51			
Units: units on scale				
least squares mean (standard error)	-2.4823 ($\pm$ 0.19606)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score Through Week 32

End point title	Change From Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score Through Week 32
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End point description:

The HAQ-DI assesses the degree of difficulty a subject has in accomplishing tasks in 8 functional areas, each scored from 0 (no difficulty) to 3 (inability to perform a task). mITT analysis set included all subjects who received at least a partial dose of the study drug. Here, 99999 signifies that no subjects were in Placebo group after Week 16 and in Placebo-CNT06785 200 mg group till Week 16. Here, 'n' signifies number of subjects analyzed for this endpoint at given timepoint.

End point type	Secondary
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End point timeframe:

Baseline up to Week 32

End point values	Placebo	CNT06785, 15 mg	CNT06785, 50 mg	CNT06785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: units on scale				
arithmetic mean (standard deviation)				
Baseline (n= 51, 52, 51, 51, 52, 0)	1.56 ($\pm$ 0.545)	1.43 ($\pm$ 0.756)	1.54 ($\pm$ 0.62)	1.49 ($\pm$ 0.736)

Change at Week 2 (n= 51, 51, 51, 50, 51, 0)	-0.19 (± 0.45)	-0.13 (± 0.409)	-0.34 (± 0.469)	-0.14 (± 0.412)
Change at Week 4 (n= 51, 52, 51, 50, 52, 0)	-0.24 (± 0.527)	-0.16 (± 0.458)	-0.28 (± 0.54)	-0.14 (± 0.485)
Change at Week 8 (n= 51, 52, 51, 51, 52, 0)	-0.27 (± 0.569)	-0.22 (± 0.559)	-0.32 (± 0.52)	-0.23 (± 0.537)
Change at Week 12 (n= 51, 52, 51, 51, 52, 0)	-0.33 (± 0.673)	-0.3 (± 0.655)	-0.42 (± 0.645)	-0.26 (± 0.452)
Change at Week 16 (n= 51, 52, 51, 51, 52, 0)	-0.38 (± 0.738)	-0.38 (± 0.657)	-0.41 (± 0.6)	-0.26 (± 0.512)
Change at Week 20 (n= 0, 52, 51, 51, 52, 51)	99999 (± 99999)	-0.34 (± 0.685)	-0.42 (± 0.668)	-0.22 (± 0.499)
Change at Week 24 (n= 0, 52, 51, 51, 52, 51)	99999 (± 99999)	-0.3 (± 0.714)	-0.42 (± 0.689)	-0.21 (± 0.509)
Change at Week 28 (n= 0, 52, 51, 51, 52, 51)	99999 (± 99999)	-0.35 (± 0.717)	-0.57 (± 0.723)	-0.23 (± 0.544)
Change at Week 32 (n= 0, 52, 51, 51, 52, 51)	99999 (± 99999)	-0.37 (± 0.714)	-0.55 (± 0.725)	-0.35 (± 0.596)

End point values	CNT06785, 200mg	Placebo- CNT06785 200mg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	51		
Units: units on scale				
arithmetic mean (standard deviation)				
Baseline (n= 51, 52, 51, 51, 52, 0)	1.44 (± 0.706)	99999 (± 99999)		
Change at Week 2 (n= 51, 51, 51, 50, 51, 0)	-0.14 (± 0.326)	99999 (± 99999)		
Change at Week 4 (n= 51, 52, 51, 50, 52, 0)	-0.15 (± 0.383)	99999 (± 99999)		
Change at Week 8 (n= 51, 52, 51, 51, 52, 0)	-0.16 (± 0.446)	99999 (± 99999)		
Change at Week 12 (n= 51, 52, 51, 51, 52, 0)	-0.24 (± 0.523)	99999 (± 99999)		
Change at Week 16 (n= 51, 52, 51, 51, 52, 0)	-0.25 (± 0.498)	99999 (± 99999)		
Change at Week 20 (n= 0, 52, 51, 51, 52, 51)	-0.27 (± 0.518)	-0.51 (± 0.722)		
Change at Week 24 (n= 0, 52, 51, 51, 52, 51)	-0.27 (± 0.585)	-0.52 (± 0.723)		
Change at Week 28 (n= 0, 52, 51, 51, 52, 51)	-0.27 (± 0.618)	-0.5 (± 0.786)		
Change at Week 32 (n= 0, 52, 51, 51, 52, 51)	-0.38 (± 0.696)	-0.55 (± 0.729)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in 36-Item Short Form Health Survey (SF-36) at Week 16

End point title	Change From Baseline in 36-Item Short Form Health Survey
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End point description:

The SF-36 is a medical outcome study health measure and consists of 8 multi-item scales that are scored from 0 to 100, with higher scores indicating better health. mITT analysis set included all subjects who received at least a partial dose of the study drug.

End point type	Secondary
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End point timeframe:

Week 16

End point values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	49	46	47
Units: units on scale				
arithmetic mean (standard deviation)				
Mental Component Score (MCS)	5.91 ($\pm$ 11.543)	6.18 ($\pm$ 12.059)	4.42 ($\pm$ 9.651)	4.05 ($\pm$ 12.323)
Physical Component Score (PCS)	5.68 ($\pm$ 8.279)	5.11 ($\pm$ 9.434)	5.33 ($\pm$ 9.191)	2.71 ($\pm$ 7.592)

End point values	CNTO6785, 200mg			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: units on scale				
arithmetic mean (standard deviation)				
Mental Component Score (MCS)	4.99 ($\pm$ 11.149)			
Physical Component Score (PCS)	3.99 ($\pm$ 7.749)			

Statistical analyses

Statistical analysis title	Statistical analysis 1 (MCS)
Comparison groups	Placebo v CNTO6785, 15 mg
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2637
Method	ANCOVA

Statistical analysis title	Statistical analysis 2 (MCS)
Comparison groups	Placebo v CNTO6785, 50 mg

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5981
Method	ANCOVA

Statistical analysis title	Statistical analysis 3 (MCS)
Comparison groups	Placebo v CNTO6785,100mg
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7214
Method	ANCOVA

Statistical analysis title	Statistical analysis 4 (MCS)
Comparison groups	Placebo v CNTO6785, 200mg
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5225
Method	ANCOVA

Statistical analysis title	Statistical analysis 5 (PCS)
Comparison groups	Placebo v CNTO6785, 15 mg
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3045
Method	ANCOVA

Statistical analysis title	Statistical analysis 6 (PCS)
Comparison groups	Placebo v CNTO6785, 50 mg
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6525
Method	ANCOVA

Statistical analysis title	Statistical analysis 7 (PCS)
Comparison groups	Placebo v CNTO6785,100mg
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1843
Method	ANCOVA

Statistical analysis title	Statistical analysis 8 (PCS)
Comparison groups	Placebo v CNTO6785, 200mg
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3753
Method	ANCOVA

Secondary: Change From Baseline in SF-36 at Week 32

End point title	Change From Baseline in SF-36 at Week 32 ^[3]
End point description: The SF-36 is a medical outcome study health measure and consists of 8 multi-item scales that are scored from 0 to 100, with higher scores indicating better health. mITT analysis set included all subjects who received at least a partial dose of the study drug.	
End point type	Secondary
End point timeframe: Baseline to Week 32	

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data was reported for the specific arms.

End point values	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785,100 mg	CNTO6785, 200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	44	39	45
Units: units on scale				
arithmetic mean (standard deviation)				
MCS	4.24 (± 12.685)	6.62 (± 8.163)	6.1 (± 12.067)	5.48 (± 11.347)
PCS	5.48 (± 9.098)	6.83 (± 8.612)	2.92 (± 9.193)	6.92 (± 9.097)

End point values	Placebo- CNTO6785 200mg			
Subject group type	Subject analysis set			
Number of subjects analysed	45			
Units: units on scale				

arithmetic mean (standard deviation)				
MCS	8.14 (± 10.831)			
PCS	8.66 (± 9.867)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Clinical Disease Activity Index (CDAI) at Week 16

End point title	Change From Baseline in Clinical Disease Activity Index (CDAI) at Week 16
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End point description:

The CDAI score is a derived score combining tender joints (28 joints), swollen joints (28 joints), patient's global assessment of disease activity, and physician's global assessments of disease activity. mITT analysis set included all subjects who received at least a partial dose of the study drug.

End point type	Secondary
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End point timeframe:

Week 16

End point values	Placebo	CNT06785, 15 mg	CNT06785, 50 mg	CNT06785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	51	51	51
Units: units on scale				
arithmetic mean (standard deviation)	-16.09 (± 15.944)	-18.58 (± 13.274)	-19.78 (± 11.392)	-17.94 (± 15.578)

End point values	CNT06785, 200mg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: units on scale				
arithmetic mean (standard deviation)	-18.41 (± 15.621)			

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v CNT06785, 15 mg

Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3159
Method	ANCOVA

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v CNTO6785, 50 mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2466
Method	ANCOVA

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v CNTO6785,100mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5866
Method	ANCOVA

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo v CNTO6785, 200mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6545
Method	ANCOVA

Secondary: Change From Baseline in CDAI at Week 32

End point title	Change From Baseline in CDAI at Week 32 ^[4]
End point description: The CDAI score is a derived score combining tender joints (28 joints), swollen joints (28 joints), patient's global assessment of disease activity, and physician's global assessments of disease activity. mITT analysis set included all subjects who received at least a partial dose of the study drug.	
End point type	Secondary
End point timeframe: Week 32	

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data was reported for the specific arms.

End point values	CNT06785, 15 mg	CNT06785, 50 mg	CNT06785,100 mg	CNT06785, 200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	51	51	50
Units: units on scale				
arithmetic mean (standard deviation)	-19.05 ($\pm$ 16.452)	-23.94 ($\pm$ 14.124)	-20.56 ($\pm$ 16.112)	-22.93 ($\pm$ 15.75)

End point values	Placebo- CNT06785 200mg			
Subject group type	Subject analysis set			
Number of subjects analysed	51			
Units: units on scale				
arithmetic mean (standard deviation)	-22.93 ($\pm$ 14.89)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Simplified Disease Activity Index (SDAI) at Week 16

End point title	Change From Baseline in Simplified Disease Activity Index (SDAI) at Week 16
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End point description:

The SDAI score is a derived score combining tender joints (28 joints), swollen joints (28 joints), patient's global assessment of disease activity, physician's global assessments of disease activity, and CRP. mITT analysis set included all subjects who received at least a partial dose of the study drug.

End point type	Secondary
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End point timeframe:

Week 16

End point values	Placebo	CNT06785, 15 mg	CNT06785, 50 mg	CNT06785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	51	50	51
Units: units on scale				
arithmetic mean (standard deviation)	-16.12 ($\pm$ 16.458)	-19.39 ($\pm$ 13.535)	-19.78 ($\pm$ 11.508)	-18.35 ($\pm$ 15.447)

End point values	CNTO6785, 200mg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: units on scale				
arithmetic mean (standard deviation)	-19.2 (± 15.739)			

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v CNTO6785, 15 mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2167
Method	ANCOVA

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v CNTO6785, 50 mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2289
Method	ANCOVA

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v CNTO6785,100mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4918
Method	ANCOVA

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo v CNTO6785, 200mg

Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.449
Method	ANCOVA

Secondary: Change From Baseline in SDAI at Week 32

End point title	Change From Baseline in SDAI at Week 32 ^[5]
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End point description:

SDAI score is a derived score combining tender joints (28 joints), swollen joints (28 joints), patient's global assessment of disease activity, physician's global assessments of disease activity, and CRP. mITT analysis set included all subjects who received at least a partial dose of the study drug.

End point type	Secondary
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End point timeframe:

Baseline to Week 32

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Data was reported for the specific arms.

End point values	CNT06785, 15 mg	CNT06785, 50 mg	CNT06785,100 mg	CNT06785, 200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	50	51	50
Units: units on scale				
arithmetic mean (standard deviation)	-19.78 (± 16.985)	-24.09 (± 14.291)	-21.24 (± 16.411)	-23.41 (± 15.888)

End point values	Placebo- CNT06785 200mg			
Subject group type	Subject analysis set			
Number of subjects analysed	51			
Units: units on scale				
arithmetic mean (standard deviation)	-23.62 (± 15.133)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With SDAI-Based ACR/European League Against Rheumatism (EULAR) Remission at Week 16

End point title	Percentage of Subjects With SDAI-Based ACR/European League Against Rheumatism (EULAR) Remission at Week 16
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End point description:

The SDAI-based ACR/EULAR remission is defined as a SDAI value of ≤3.3 at a visit. mITT analysis set

included all subjects who received at least a partial dose of the study drug.

End point type	Secondary
End point timeframe:	
Week 16	

End point values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785,100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: Percentage of subjects				
number (not applicable)	3.9	5.8	5.9	5.9

End point values	CNTO6785, 200mg			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Percentage of subjects				
number (not applicable)	1.9			

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v CNTO6785, 15 mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6527
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v CNTO6785, 50 mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6651
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v CNTO6785,100mg

Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6512
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo v CNTO6785, 200mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5487
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Subjects With SDAI-Based ACR/EULAR Remission at Week 32

End point title	Percentage of Subjects With SDAI-Based ACR/EULAR Remission at Week 32 ^[6]
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End point description:

SDAI-based ACR/EULAR remission is defined as a SDAI value of ≤ 3.3 at a visit. mITT analysis set included all subjects who received at least a partial dose of the study drug.

End point type	Secondary
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End point timeframe:

Week 32

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data was reported for the specific arms.

End point values	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785, 100 mg	CNTO6785, 200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	51	51	52
Units: Percentage of subjects				
number (not applicable)	13.5	13.7	11.8	15.4

End point values	Placebo- CNTO6785 200mg			
Subject group type	Subject analysis set			
Number of subjects analysed	51			
Units: Percentage of subjects				
number (not applicable)	7.8			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Boolean-Based ACR/EULAR Remission at Week 16

End point title	Percentage of Subjects With Boolean-Based ACR/EULAR Remission at Week 16
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End point description:

The Boolean-based ACR/EULAR remission is achieved if all of the following 4 criteria at that visit are met: tender joint count (68 joints) ≤ 1 ; swollen joint count (66 joints) ≤ 1 ; CRP ≤ 1 milligram per deciliter (mg/dL); and patient's global assessment of disease activity on visual analog scale (VAS) ≤ 1 on a 0 to 10 scale. mITT analysis set included all subjects who received at least a partial dose of the study drug.

End point type	Secondary
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End point timeframe:

Week 16

End point values	Placebo	CNTO6785, 15 mg	CNTO6785, 50 mg	CNTO6785, 100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	52	51	51
Units: Percentage of subjects				
number (not applicable)	3.9	5.8	5.9	3.9

End point values	CNTO6785, 200mg			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: Percentage of subjects				
number (not applicable)	1.9			

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v CNTO6785, 15 mg

Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6394
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v CNTO6785, 50 mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.657
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v CNTO6785,100mg
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo v CNTO6785, 200mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5524
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Subjects With Boolean-Based ACR/EULAR Remission at Week 32

End point title	Percentage of Subjects With Boolean-Based ACR/EULAR Remission at Week 32 ^[7]
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End point description:

The Boolean-based ACR/EULAR remission is achieved if all of the following 4 criteria at that visit are met: tender joint count (68 joints) ≤ 1 ; swollen joint count (66 joints) ≤ 1 ; CRP ≤ 1 mg/dL; and patient's global assessment of disease activity on VAS ≤ 1 on a 0 to 10 scale. mITT analysis set included all subjects who received at least a partial dose of the study drug.

End point type	Secondary
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End point timeframe:

Week 32

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data was reported for the specific arms.

End point values	CNT06785, 15 mg	CNT06785, 50 mg	CNT06785,100 mg	CNT06785, 200mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	51	51	52
Units: Percentage of subjects				
number (not applicable)	11.5	9.8	5.9	7.7

End point values	Placebo- CNT06785 200mg			
Subject group type	Subject analysis set			
Number of subjects analysed	51			
Units: Percentage of subjects				
number (not applicable)	3.9			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline to follow-up (Week 38)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.1
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Reporting groups

Reporting group title	Placebo (Week 0-Week 16)
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Reporting group description:

Subject administered with Placebo subcutaneous injections (SC) every 4 weeks through Week 12.

Reporting group title	Placebo->200 mg (Week 16-Week 38)
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Reporting group description:

Patients receiving Placebo at Week 0, 4,8,12 --> receiving 200 mg CNTO6785 at Week 16 and every 4 weeks (q4w) thereafter through Week 28

Reporting group title	CNTO6785, 15 mg (Week 0-Week 38)
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Reporting group description:

Subjects received 15 mg of CNTO6785 as SC every 4 weeks through Week 28.

Reporting group title	CNTO6785, 50 mg (Week 0-Week 38)
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Reporting group description:

Subjects received 50 mg of CNTO6785 as SC every 4 weeks through Week 28.

Reporting group title	CNTO6785, 100 mg (Week 0-Week 38)
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Reporting group description:

Subjects received 100 mg of CNTO6785 as SC every 4 weeks through Week 28.

Reporting group title	CNTO6785, 200 mg (Week 0-Week 38)
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Reporting group description:

Subjects received 200 mg of CNTO6785 as SC every 4 weeks through Week 28.

Serious adverse events	Placebo (Week 0-Week 16)	Placebo->200 mg (Week 16-Week 38)	CNTO6785, 15 mg (Week 0-Week 38)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 51 (1.96%)	1 / 48 (2.08%)	2 / 52 (3.85%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast Cancer Stage Iii			
subjects affected / exposed	0 / 51 (0.00%)	0 / 48 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Joint Injury			

subjects affected / exposed	0 / 51 (0.00%)	0 / 48 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	1 / 51 (1.96%)	0 / 48 (0.00%)	0 / 52 (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
Nervous system disorders			
Cerebrovascular Accident			
subjects affected / exposed	0 / 51 (0.00%)	0 / 48 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 48 (0.00%)	0 / 52 (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
Cholecystitis Acute			
subjects affected / exposed	0 / 51 (0.00%)	0 / 48 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Prerenal Failure			
subjects affected / exposed	1 / 51 (1.96%)	0 / 48 (0.00%)	0 / 52 (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
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 48 (0.00%)	0 / 52 (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
Rheumatoid Arthritis			

subjects affected / exposed	0 / 51 (0.00%)	0 / 48 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Pain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 48 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 51 (0.00%)	1 / 48 (2.08%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	CNT06785, 50 mg (Week 0-Week 38)	CNT06785, 100 mg (Week 0-Week 38)	CNT06785, 200 mg (Week 0-Week 38)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 51 (3.92%)	5 / 51 (9.80%)	0 / 52 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast Cancer Stage Iii			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 52 (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
Injury, poisoning and procedural complications			
Joint Injury			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Cerebrovascular Accident			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	0 / 52 (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
Cholecystitis Acute			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	0 / 52 (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
Renal and urinary disorders			
Acute Prerenal Failure			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 52 (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			
Osteoarthritis			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	0 / 52 (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
Rheumatoid Arthritis			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Pain			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo (Week 0-Week 16)	Placebo->200 mg (Week 16-Week 38)	CNT06785, 15 mg (Week 0-Week 38)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 51 (11.76%)	17 / 48 (35.42%)	19 / 52 (36.54%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 51 (1.96%)	1 / 48 (2.08%)	1 / 52 (1.92%)
occurrences (all)	1	1	1
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 51 (1.96%)	1 / 48 (2.08%)	1 / 52 (1.92%)
occurrences (all)	1	1	1
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 51 (3.92%)	1 / 48 (2.08%)	3 / 52 (5.77%)
occurrences (all)	3	1	3
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 48 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 48 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	0 / 51 (0.00%)	2 / 48 (4.17%)	1 / 52 (1.92%)
occurrences (all)	0	4	1
Injection Site Pain			
subjects affected / exposed	1 / 51 (1.96%)	6 / 48 (12.50%)	8 / 52 (15.38%)
occurrences (all)	1	11	23
Musculoskeletal and connective tissue disorders			

Rheumatoid Arthritis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	1 / 48 (2.08%) 1	4 / 52 (7.69%) 5
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	1 / 48 (2.08%) 1	2 / 52 (3.85%) 2
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	1 / 48 (2.08%) 1	0 / 52 (0.00%) 0
Pharyngitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	3 / 48 (6.25%) 3	4 / 52 (7.69%) 4
Respiratory Tract Infection subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 48 (0.00%) 0	0 / 52 (0.00%) 0
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	3 / 51 (5.88%) 3	1 / 48 (2.08%) 1	0 / 52 (0.00%) 0
Urinary Tract Infection subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 2	2 / 48 (4.17%) 2	5 / 52 (9.62%) 5

Non-serious adverse events	CNT06785, 50 mg (Week 0-Week 38)	CNT06785, 100 mg (Week 0-Week 38)	CNT06785, 200 mg (Week 0-Week 38)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 51 (41.18%)	28 / 51 (54.90%)	20 / 52 (38.46%)
Investigations			
Alanine Aminotransferase Increased subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	4 / 51 (7.84%) 4	5 / 52 (9.62%) 6
Aspartate Aminotransferase Increased subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1	5 / 52 (9.62%) 5
Vascular disorders			
Hypertension			

subjects affected / exposed occurrences (all)	3 / 51 (5.88%) 3	3 / 51 (5.88%) 4	2 / 52 (3.85%) 2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	3
Leukocytosis			
subjects affected / exposed	0 / 51 (0.00%)	3 / 51 (5.88%)	0 / 52 (0.00%)
occurrences (all)	0	3	0
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	1 / 51 (1.96%)	4 / 51 (7.84%)	2 / 52 (3.85%)
occurrences (all)	1	15	12
Injection Site Pain			
subjects affected / exposed	11 / 51 (21.57%)	8 / 51 (15.69%)	9 / 52 (17.31%)
occurrences (all)	35	22	38
Musculoskeletal and connective tissue disorders			
Rheumatoid Arthritis			
subjects affected / exposed	1 / 51 (1.96%)	3 / 51 (5.88%)	3 / 52 (5.77%)
occurrences (all)	1	3	4
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 51 (3.92%)	3 / 51 (5.88%)	0 / 52 (0.00%)
occurrences (all)	2	3	0
Nasopharyngitis			
subjects affected / exposed	3 / 51 (5.88%)	1 / 51 (1.96%)	0 / 52 (0.00%)
occurrences (all)	3	1	0
Pharyngitis			
subjects affected / exposed	4 / 51 (7.84%)	2 / 51 (3.92%)	1 / 52 (1.92%)
occurrences (all)	4	2	1
Respiratory Tract Infection			
subjects affected / exposed	1 / 51 (1.96%)	3 / 51 (5.88%)	0 / 52 (0.00%)
occurrences (all)	1	3	0
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 51 (3.92%)	5 / 51 (9.80%)	3 / 52 (5.77%)
occurrences (all)	4	5	4

Urinary Tract Infection subjects affected / exposed occurrences (all)	2 / 51 (3.92%) 2	3 / 51 (5.88%) 5	2 / 52 (3.85%) 2
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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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None reported

Notes: