Clinical trial results:
A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, an Anti-TNF Monoclonal Antibody, Administered Intravenously, in Subjects with Active Psoriatic Arthritis

Summary

EudraCT number	2014-000242-30
Trial protocol	DE LT ES HU
Global end of trial date	22 March 2017

Results information

Result version number	v1 (current)
This version publication date	07 April 2018
First version publication date	07 April 2018

Trial information

Trial identification

Sponsor protocol code	CNTO148PSA3001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02181673
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Biologics, BV
Sponsor organisation address	Archimedesweg 29, Leiden, Netherlands, 2333CM
Public contact	Clinical Registry Group, Janssen Biologics, BV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Biologics, BV, 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	22 March 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 March 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the efficacy of intravenous (IV) administration of golimumab 2 milligram per kilogram (mg/kg) in subjects with active psoriatic arthritis (PsA) by assessing the reduction in signs and symptoms of PsA.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. Safety evaluations included measurement of vital signs, assessment of adverse events (AEs), physical examinations, electrocardiogram (screening only), concomitant medications, infusion reaction evaluations, and assessments of allergic reactions and infections. Tuberculosis (TB) was also performed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 September 2014
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	Belarus: 22
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	Spain: 3
Country: Number of subjects enrolled	Hungary: 22
Country: Number of subjects enrolled	Lithuania: 30
Country: Number of subjects enrolled	Poland: 77
Country: Number of subjects enrolled	Romania: 4
Country: Number of subjects enrolled	Russian Federation: 153
Country: Number of subjects enrolled	Ukraine: 147
Country: Number of subjects enrolled	United States: 17
Worldwide total number of subjects	480
EEA total number of subjects	140

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)	446
From 65 to 84 years	34
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

817 subjects were screened and 480 subjects were randomized to treatment (241 to golimumab 2 milligram per kilogram [mg/kg] and 239 to placebo).

Period 1

Period 1 title	Up to Week 24
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 (week 0-24)

Arm description:

Subjects received intravenous infusions of placebo at Weeks 0, 4, 12 and 20.

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

Dosage and administration details:

Subjects received intravenous infusions of placebo at Weeks 0, 4, 12 and 20.

Arm title	Golimumab 2 mg/kg (Week 0-60)

Arm description:

Subjects were randomized to receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and every 8 weeks thereafter up to Week 52. At Week 24, subjects received a placebo intravenous infusion to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Placebo IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received a placebo intravenous infusion at week 24 to maintain the blind.

Investigational medicinal product name	Golimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects were randomized to receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and every 8 weeks thereafter up to Week 52.

Number of subjects in period 1	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)
Started	239	241
Treated	239	240
Completed	222	230
Not completed	17	11
Consent withdrawn by subject	10	1
Physician decision	-	3
Adverse event, non-fatal	2	3
Death	1	-
Unspecified	2	3
Lost to follow-up	1	-
Randomized not Treated	-	1
Lack of efficacy	1	-

Period 2

Period 2 title	Week 24-Week 60
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo then Golimumab 2 mg/kg (Week 24-60)

Arm description:

Subjects who received placebo up to Week 20 were then crossed over at Week 24 to receive intravenous infusions of golimumab 2 milligram per kilogram (mg/kg) at Week 24, 28 and every 8 weeks thereafter up to Week 52.

Arm type	Experimental
Investigational medicinal product name	Golimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects who received placebo up to Week 20 were then crossed over at Week 24 to receive intravenous infusions of golimumab 2 milligram per kilogram (mg/kg) at Week 24, 28 and every 8 weeks thereafter up to Week 52.

Arm title	Golimumab 2 mg/kg (Week 0-60)

Arm description:

Subjects were randomized to receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and

every 8 weeks thereafter up to Week 52. At Week 24, subjects received a placebo intravenous infusion to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Golimumab 2 mg/kg (Week 0-60)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects were randomized to receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and every 8 weeks thereafter up to Week 52. At Week 24, subjects received a placebo intravenous infusion to maintain the blind.

Number of subjects in period 2	Placebo then Golimumab 2 mg/kg (Week 24-60)	Golimumab 2 mg/kg (Week 0-60)
Started	222	230
Treated	220	230
Completed	214	213
Not completed	8	17
Consent withdrawn by subject	2	2
Physician decision	-	1
Adverse event, non-fatal	4	10
Pregnancy	-	1
Unspecified	2	1
Lost to follow-up	-	1
Lack of efficacy	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo (week 0-24)
Reporting group description:	
Subjects received intravenous infusions of placebo at Weeks 0, 4, 12 and 20.	
Reporting group title	Golimumab 2 mg/kg (Week 0-60)
Reporting group description:	
Subjects were randomized to receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and every 8 weeks thereafter up to Week 52. At Week 24, subjects received a placebo intravenous infusion to maintain the blind.	

Reporting group values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)	Total
Number of subjects	239	241	480
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	218	228	446
From 65 to 84 years	21	13	34
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	46.7	45.7	
standard deviation	± 12.53	± 11.25	-
Title for Gender Units: subjects			
Female	118	113	231
Male	121	128	249

End points

End points reporting groups

Reporting group title	Placebo (week 0-24)
Reporting group description:	
Subjects received intravenous infusions of placebo at Weeks 0, 4, 12 and 20.	
Reporting group title	Golimumab 2 mg/kg (Week 0-60)
Reporting group description:	
Subjects were randomized to receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and every 8 weeks thereafter up to Week 52. At Week 24, subjects received a placebo intravenous infusion to maintain the blind.	
Reporting group title	Placebo then Golimumab 2 mg/kg (Week 24-60)
Reporting group description:	
Subjects who received placebo up to Week 20 were then crossed over at Week 24 to receive intravenous infusions of golimumab 2 milligram per kilogram (mg/kg) at Week 24, 28 and every 8 weeks thereafter up to Week 52.	
Reporting group title	Golimumab 2 mg/kg (Week 0-60)
Reporting group description:	
Subjects were randomized to receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and every 8 weeks thereafter up to Week 52. At Week 24, subjects received a placebo intravenous infusion to maintain the blind.	

Primary: Percentage of Subjects who Achieved an American College of Rheumatology (ACR) 20 Response at Week 14

End point title	Percentage of Subjects who Achieved an American College of Rheumatology (ACR) 20 Response at Week 14
End point description:	
The ACR 20 response is defined as greater than or equal to (>=) 20 percent (%) improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints) and >=20% improvement from baseline in at least 3 of the following 5 assessments: Patient's assessment of pain (on a 0 to 10 centimeter [cm] scale), Patient's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Physician's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Patient's assessment of physical function as measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI) and measurement of a blood test called C-reactive protein (CRP). The full analysis set (FAS) included all subjects who were randomized.	
End point type	Primary
End point timeframe:	
Week 14	

End point values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	239	241		
Units: Percentage of subjects				
number (not applicable)	21.8	75.1		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo (week 0-24) v Golimumab 2 mg/kg (Week 0-60)
Number of subjects included in analysis	480
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Percent Difference
Point estimate	53.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	45.8
upper limit	60.9

Secondary: Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score at Week 14

End point title	Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score at Week 14

End point description:

The Health Assessment Questionnaire-Disability Index (HAQ-DI) is a 20-question instrument that assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping and activities of daily living). Responses in each functional area are scored from 0 to 3 (0=no difficulty and 3=inability to perform a task in that area). Overall score was computed as the sum of domain scores and divided by the number of domains answered. Total possible score range 0-3 where 0 = least difficulty and 3 = extreme difficulty. The FAS included all subjects who were randomized. Here "N" (number of subjects analyzed) signifies the number of subjects who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline and Week 14

End point values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	233		
Units: Units on a scale				
median (standard deviation)	-0.12 (± 0.466)	-0.60 (± 0.530)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved an ACR 50 Response at Week 14

End point title	Percentage of Subjects who Achieved an ACR 50 Response at Week 14

End point description:

The ACR 50 response is defined as: greater than or equal to (>=) 50 percent (%) improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints) and >=50% improvement from baseline in at least 3 of the following 5 assessments: Patient's assessment of pain (on a 0 to 10 cm scale), Patient's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Physician's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Patient's assessment of physical function as measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI) and measurement of a blood test called C-reactive protein (CRP). The FAS included all subjects who were randomized.

End point type	Secondary

End point timeframe:

Week 14

End point values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	239	241		
Units: Percentage of subjects				
number (not applicable)	6.3	43.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Psoriatic Area and Severity Index (PASI) 75 Response at Week 14

End point title	Percentage of Subjects who Achieved Psoriatic Area and Severity Index (PASI) 75 Response at Week 14

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 75 response represents subjects who achieved at least a 75 % improvement from baseline in the PASI score. The analysis set included randomized subjects with >= 3 % body surface area (BSA) psoriasis skin involvement at baseline. The FAS included all subjects who were randomized. Here "N" (number of subjects analyzed) signifies the
number of subjects who were evaluable for this outcome measure

End point type	Secondary

End point timeframe:

Week 14

End point values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	198	196		
Units: Percentage of subjects				
number (not applicable)	13.6	59.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Total Modified Van Der Heijde-Sharp (vdH-S) Score at Week 24

End point title	Change from Baseline in Total Modified Van Der Heijde-Sharp (vdH-S) Score at Week 24

End point description:

The modified vdH-S score is a radiographic evaluation of hand and feet erosions and joint space narrowing (JSN) for 20 joints per hand and 6 joints per foot with a total score ranging from 0 (best) to 528 (worst = worst possible erosion score of 320 + worst possible JSN score of 208). Higher score and positive score changes indicate more radiographic damage and radiographic progression, respectively. FAS for structural damage endpoints (FAS-SD) defined as subjects who were randomized and treated and had a non-missing baseline total modified vdH-S score for the analysis.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	237	237		
Units: Units on scale				
arithmetic mean (standard error)	1.95 (± 0.264)	-0.36 (± 0.144)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Leeds Enthesitis Index (LEI) at Week 14 in Subjecs With Enthesitis at Baseline

End point title	Change from Baseline in Leeds Enthesitis Index (LEI) at Week 14 in Subjecs With Enthesitis at Baseline

End point description:

Enthesitis will be assessed using the Leeds Enthesitis Index (LEI). The LEI was developed to assess enthesitis in subjects with PsA, and evaluates the presence (score of 1) or absence of pain (score of 0) by applying local pressure to Lateral elbow epicondyle, left and right, Medial femoral condyle, left and right, and Achilles tendon insertion, left and right. LEI scores ranging from 0 (0 sites with tenderness) to

6 (worst possible score; 6 sites with tenderness). Population included all randomized subjects with Enthesitis at Baseline. Here "N" (number of subjects analyzed) signifies the number of subjects who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline and Week 14

End point values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	173	182		
Units: Units on scale				
arithmetic mean (standard deviation)	-0.8 (± 1.98)	-1.8 (± 1.75)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Dactylitis Scores at Week 14 in Subjects With Dactylitis at Baseline

End point title	Change from Baseline in Dactylitis Scores at Week 14 in Subjects With Dactylitis at Baseline

End point description:

Dactylitis is characterized by swelling of the entire finger or toe. The severity of dactylitis is scored on a scale of 0-3, where 0=tenderness and 3=extreme tenderness in each digit of the hands and feet. The range of total dactylitis scores for a subject is 0-60. Higher score indicates greater degree of tenderness. Population included all Randomized subjectss With Dactylitis (Score >0) at Baseline. Here "N" (number of subjects analyzed) signifies the number of subjects who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline and Week 14

End point values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	115	130		
Units: Units on scale				
arithmetic mean (standard deviation)	-2.8 (± 7.03)	-7.8 (± 8.57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Short Form-36 Health Survey (SF-36) Physical Component Summary (PCS) at Week 14

End point title	Change from Baseline in Short Form-36 Health Survey (SF-36) Physical Component Summary (PCS) at Week 14

End point description:

The Medical Outcome Study health measure SF-36 questionnaire is a well-validated and widely used quality-of-life instrument. It is a self-administered survey that consists of 8 multi-item scales: The 4 subscales of the SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and general health) and the 4 subscales of the SF-36 comprises the MCS score (vitality, social functioning, role-emotional, and mental health). PCS and MCS are scored from 0 to 100 with higher scores indicating better health (worst value is 0 and best value is 100), which are scored using a norm-based system where linear transformations are performed to transform scores to a mean of 50 and standard deviation of 10. FAS included all subjects who were randomized in the study. Here, 'N' (number of subjects analyzed) signifies number of subjects who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline and Week 14

End point values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	233		
Units: Units on scale				
arithmetic mean (standard deviation)	2.69 (± 5.920)	8.65 (± 7.602)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an American College of Rheumatology (ACR) 50 Response at Week 24

End point title	Percentage of Subjects Who Achieved an American College of Rheumatology (ACR) 50 Response at Week 24

End point description:

The ACR 50 response is defined as >= 50 % improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints) and >=50% improvement from baseline in at least 3 of the following 5 assessments: Patient's assessment of pain (on a 0 to 10 centimeter [cm] scale), Patient's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Physician's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Patient's assessment of physical function as measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI) and measurement of a blood test called C-reactive protein (CRP). The FAS included all subjects who were randomized.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	239	241		
Units: Percentage of subjects				
number (not applicable)	6.3	53.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an American College of Rheumatology (ACR) 70 Response at Week 14

End point title	Percentage of Subjects Who Achieved an American College of Rheumatology (ACR) 70 Response at Week 14

End point description:

The ACR 70 response is defined as >= 70 % improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints) and >=70% improvement from baseline in at least 3 of the following 5 assessments: Patient's assessment of pain (on a 0 to 10 centimeter [cm] scale), Patient's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Physician's Global Assessment of Disease Activity (on a 0 to 10 cm scale),Patient's assessment of physical function as measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI) and measurement of a blood test called C-reactive protein (CRP). The FAS included all subjects who were randomized.

End point type	Secondary

End point timeframe:

Week 14

End point values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	239	241		
Units: Percentage of subjects				
number (not applicable)	2.1	24.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Short Form-36 Health Survey (SF)-36 Mental Component Summary (MCS) at Week 14

End point title	Change from Baseline in Short Form-36 Health Survey (SF)-36 Mental Component Summary (MCS) at Week 14

End point description:

The Medical Outcome Study health measure SF-36 questionnaire is a well-validated and widely used quality-of-life instrument. It is a self-administered survey that consists of 8 multi-item scales: The 4 subscales of the SF-36 comprises the PCS score (physical functioning, role-physical, bodily pain, and

general health) and the 4 subscales of the SF-36 comprises the MCS score(vitality, social functioning, role-emotional, and mental health). PCS and MCS are scored from 0 to 100 with higher scores indicating better health (worst value is 0 and best value is 100), which are scored using a norm-based system where linear transformations are performed to transform scores to a mean of 50 and standard deviation of 10. FAS included all subjects who were randomized in the study. Here, 'N' (number of subjects analyzed) signifies number of subjects who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline and Week 14

End point values	Placebo (week 0-24)	Golimumab 2 mg/kg (Week 0-60)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	233		
Units: Units on a scale				
arithmetic mean (standard deviation)	0.97 (± 7.644)	5.33 (± 9.948)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to 60 Weeks	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups	
Reporting group title	Placebo (Week 0-24)
Reporting group description:	
Subjects received intravenous infusions of placebo at Weeks 0, 4, 12 and 20.	
Reporting group title	Golimumab 2 mg/kg (Week 0-60)
Reporting group description:	
Subjects were randomized to receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and every 8 weeks thereafter up to Week 52. At Week 24, subjects received a placebo intravenous infusion to maintain the blind.	
Reporting group title	Placebo Then Golimumab 2 mg/kg (Week 24-60)
Reporting group description:	
Subjects who received placebo up to Week 20 were then crossed over at Week 24 to receive intravenous infusions of golimumab 2 milligram per kilogram (mg/kg) at Week 24, 28 and every 8 weeks thereafter up to Week 52.	

Serious adverse events	Placebo (Week 0-24)	Golimumab 2 mg/kg (Week 0-60)	Placebo Then Golimumab 2 mg/kg (Week 24-60)
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 239 (3.35%)	19 / 240 (7.92%)	5 / 220 (2.27%)
number of deaths (all causes)	2	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Gastric cancer			
subjects affected / exposed	0 / 239 (0.00%)	0 / 240 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma benign			

subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Non-small cell lung cancer			
subjects affected / exposed	1 / 239 (0.42%)	0 / 240 (0.00%)	0 / 220 (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
Oesophageal neoplasm			
subjects affected / exposed	1 / 239 (0.42%)	0 / 240 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pleomorphic adenoma			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 240 (0.00%)	0 / 220 (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
Hypertension			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Hypertensive crisis			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pneumonia aspiration			
subjects affected / exposed	1 / 239 (0.42%)	0 / 240 (0.00%)	0 / 220 (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

Investigations			
Gene mutation identification test positive			
subjects affected / exposed	0 / 239 (0.00%)	0 / 240 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laboratory test abnormal			
subjects affected / exposed	0 / 239 (0.00%)	0 / 240 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	1 / 239 (0.42%)	1 / 240 (0.42%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Epidural haemorrhage			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Facial bones fracture			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Humerus fracture			
subjects affected / exposed	1 / 239 (0.42%)	1 / 240 (0.42%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Skull fracture			

subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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			
Cardiac failure acute			
subjects affected / exposed	1 / 239 (0.42%)	0 / 240 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haematoma			
subjects affected / exposed	1 / 239 (0.42%)	0 / 240 (0.00%)	0 / 220 (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
Headache			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Neuritis			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Paraesthesia			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Eye disorders			
Cataract			
subjects affected / exposed	1 / 239 (0.42%)	0 / 240 (0.00%)	0 / 220 (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			
Oedematous pancreatitis			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Hepatitis acute			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatitis chronic active			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Skin and subcutaneous tissue disorders			
Pustular psoriasis			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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 failure			
subjects affected / exposed	1 / 239 (0.42%)	0 / 240 (0.00%)	0 / 220 (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
Infections and infestations			
Empyema			

subjects affected / exposed	0 / 239 (0.00%)	0 / 240 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected dermal cyst			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Periodontitis			
subjects affected / exposed	0 / 239 (0.00%)	0 / 240 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 239 (0.42%)	2 / 240 (0.83%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 239 (0.00%)	2 / 240 (0.83%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 239 (0.00%)	1 / 240 (0.42%)	0 / 220 (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
Urinary tract infection			
subjects affected / exposed	0 / 239 (0.00%)	0 / 240 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
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 0-24)	Golimumab 2 mg/kg (Week 0-60)	Placebo Then Golimumab 2 mg/kg (Week 24-60)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 239 (7.95%)	40 / 240 (16.67%)	25 / 220 (11.36%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	5 / 239 (2.09%)	25 / 240 (10.42%)	13 / 220 (5.91%)
occurrences (all)	5	31	13
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 239 (2.09%)	19 / 240 (7.92%)	12 / 220 (5.45%)
occurrences (all)	5	24	12
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	13 / 239 (5.44%)	14 / 240 (5.83%)	9 / 220 (4.09%)
occurrences (all)	14	16	10

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