Clinical trial results:
A Phase 2a Open-label Study to Evaluate Prediction of Response to Golimumab Using a Transcriptomic Profile in Subjects with Moderately to Severely Active Ulcerative Colitis

Summary

EudraCT number	2013-002042-36
Trial protocol	BE HU CZ BG PL DE NL FR
Global end of trial date	29 January 2016

Results information

Result version number	v1 (current)
This version publication date	21 January 2017
First version publication date	21 January 2017

Trial information

Trial identification

Sponsor protocol code	CNTO148UCO2001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01988961
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Biologics B.V.
Sponsor organisation address	Einsteinweg 101, Leiden, Netherlands, 2333 CB
Public contact	Clinical Registry Group-JB BV, Janssen Research and Development, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group-JB BV, Janssen Research and Development, 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	29 January 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 January 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the study was to evaluate the accuracy of the length-109 (subsequently defined as the length-13) probe set panel in predicting mucosal healing (ie, improvement in the endoscopic appearance of the mucosa) at Week 6 as measured by the area under a Receiver Operating Characteristic (ROC) curve (AUCROC).

Protection of trial subjects:

The safety assessments included adverse events (AEs), clinical laboratory data (hematology, serum chemistry, antinuclear antibody [ANA] and anti-double-stranded deoxyribonucleic acid [dsDNA] antibodies, Immunogenicity and Injection-site Reactions).

Background therapy:

Subjects could have been receiving concomitant treatment with 5-aminosalicylates (5-ASAs), corticosteroids, and /or immunomodulators {(ie. 6-mercaptopurine (6-MP), azathioprine (AZA), or methotrexate (MTX)}.

Evidence for comparator: -

Actual start date of recruitment	10 February 2014
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	Belgium: 2
Country: Number of subjects enrolled	Bulgaria: 3
Country: Number of subjects enrolled	Canada: 15
Country: Number of subjects enrolled	Czech Republic: 6
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Poland: 21
Country: Number of subjects enrolled	Russian Federation: 2
Country: Number of subjects enrolled	Ukraine: 7
Country: Number of subjects enrolled	United States: 41
Worldwide total number of subjects	103
EEA total number of subjects	38

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)	98
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted from 10 February 2014 to 29 January 2016.

Pre-assignment

Screening details:

A total of 103 subjects were enrolled in study among these subjects 3 subjects received no maintenance treatment and 100 subjects received maintenance treatment.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Golimumab Induction Only

Arm description:

All subjects only received golimumab induction subcutaneous (SC) dose of 200 milligram (mg) at week 0 followed by 100 mg at week 2. No maintenance dose given to subjects in this reporting group.

Arm type	Experimental
Investigational medicinal product name	Golimumab 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received golimumab SC dose of 200 mg as 2 pre-filled syringes of 100 mg each at week 0.

Investigational medicinal product name	Golimumab 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received golimumab SC dose of 100 mg at week 2.

Arm title	Golimumab Induction + 50 mg maintenance

Arm description:

Subjects received golimumab induction SC dose of 200 mg at week 0 and 100 mg at week 2 followed by SC maintenance dose of golimumab 50 mg at week 6 and every 4 weeks (q4w) thereafter through week 50.

Arm type	Experimental
Investigational medicinal product name	Golimumab 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received golimumab SC dose of 200 mg as 2 pre-filled syringes of 100 mg each at week 0.

Investigational medicinal product name	Golimumab 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received golimumab SC dose of 100 mg at week 2.

Investigational medicinal product name	Golimumab 50 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received golimumab SC dose of 50 mg at week 6 and q4w thereafter through week 50.

Arm title	Golimumab induction + 100 mg maintenance

Arm description:

Subjects received golimumab induction SC dose of 200 mg at week 0 and 100 mg at week 2 followed by SC maintenance dose of golimumab 100 mg at week 6 and every 4 weeks (q4w) thereafter through week 50.

Arm type	Experimental
Investigational medicinal product name	Golimumab 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received golimumab SC dose of 200 mg as 2 pre-filled syringes of 100 mg each at week 0.

Investigational medicinal product name	Golimumab 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received golimumab SC dose of 100 mg at week 2 as induction dose followed by 100 mg dose at week 6 and q4w thereafter through week 50 as maintenance dose.

Number of subjects in period 1	Golimumab Induction Only	Golimumab Induction + 50 mg maintenance	Golimumab induction + 100 mg maintenance
Started	3	24	76
Completed	0	21	63
Not completed	3	3	13
Consent withdrawn by subject	1	-	3
Other	1	3	10
Lost to follow-up	1	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Golimumab Induction Only
Reporting group description:	
All subjects only received golimumab induction subcutaneous (SC) dose of 200 milligram (mg) at week 0 followed by 100 mg at week 2. No maintenance dose given to subjects in this reporting group.	
Reporting group title	Golimumab Induction + 50 mg maintenance
Reporting group description:	
Subjects received golimumab induction SC dose of 200 mg at week 0 and 100 mg at week 2 followed by SC maintenance dose of golimumab 50 mg at week 6 and every 4 weeks (q4w) thereafter through week 50.	
Reporting group title	Golimumab induction + 100 mg maintenance
Reporting group description:	
Subjects received golimumab induction SC dose of 200 mg at week 0 and 100 mg at week 2 followed by SC maintenance dose of golimumab 100 mg at week 6 and every 4 weeks (q4w) thereafter through week 50.	

Reporting group values	Golimumab Induction Only	Golimumab Induction + 50 mg maintenance	Golimumab induction + 100 mg maintenance
Number of subjects	3	24	76
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	23	72
From 65 to 84 years	0	1	4
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	46	37.5	43.3
standard deviation	± 21.66	± 15.09	± 13.36
Title for Gender Units: subjects			
Female	1	13	32
Male	2	11	44

Reporting group values	Total		
Number of subjects	103		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	98		
From 65 to 84 years	5		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		

Title for Gender Units: subjects			
Female	46		
Male	57		

End points

End points reporting groups

Reporting group title	Golimumab Induction Only

Reporting group description:

All subjects only received golimumab induction subcutaneous (SC) dose of 200 milligram (mg) at week 0 followed by 100 mg at week 2. No maintenance dose given to subjects in this reporting group.

Reporting group title	Golimumab Induction + 50 mg maintenance

Reporting group description:

Subjects received golimumab induction SC dose of 200 mg at week 0 and 100 mg at week 2 followed by SC maintenance dose of golimumab 50 mg at week 6 and every 4 weeks (q4w) thereafter through week 50.

Reporting group title	Golimumab induction + 100 mg maintenance

Reporting group description:

Subjects received golimumab induction SC dose of 200 mg at week 0 and 100 mg at week 2 followed by SC maintenance dose of golimumab 100 mg at week 6 and every 4 weeks (q4w) thereafter through week 50.

Subject analysis set title	Biomarker analysis set
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

The biomarker analysis set consisted of all treated subjects (subjects who received at least 1 [partial or complete] administration of golimumab) who had their biomarker measurement at baseline.

Primary: The Area Under the Receiver Operating Characteristic Curve (AUCROC) of a Subset of the Length-109 Probe set Panel as a Predictor of Mucosal Healing at Week 6

End point title	The Area Under the Receiver Operating Characteristic Curve (AUCROC) of a Subset of the Length-109 Probe set Panel as a Predictor of Mucosal Healing at Week 6[1]

End point description:

The area under the Receiver Operating Characteristic curve is a mathematical model used to measure the accuracy of a test. The accuracy of a subset of the length-109 probe set panel (a genetic test administered at screening) is being evaluated in terms of its ability to predict mucosal healing at Week 6. An area of 1.0 represents a perfect test; an area of 0.5 represents a test that is no better at predicting mucosal healing than "flipping a coin". Areas above 0.5 represent increasing accuracy. The accuracy of the length-13 probe set panel in predicting mucosal healing at Week 6 is significantly greater than 0.5 (AUCROC: 0.688; lower bound of 95% CI: 0.589; p-value=0.002).

End point type	Primary

End point timeframe:

Week 6

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis involving treatment comparisons is not reported for this endpoint as the analysis is based on biomarker analysis set without treatment comparisons.

End point values	Biomarker analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	93[2]			
Units: probability				
number (not applicable)	0.688			

Notes:

[2] - Biomarker analysis set

Statistical analyses

No statistical analyses for this end point

Secondary: The Area Under the Receiver Operating Characteristic Curve of a Subset of the Length-109 Probe set Panel as a Predictor of Clinical Response at Week 6 and at Week 30

End point title	The Area Under the Receiver Operating Characteristic Curve of a Subset of the Length-109 Probe set Panel as a Predictor of Clinical Response at Week 6 and at Week 30

End point description:

The area under the Receiver Operating Characteristic curve is a mathematical model used to measure the accuracy of a test. The accuracy of a subset of the length-109 probe set panel (a genetic test administered at screening) is being evaluated in terms of its ability to predict clinical response. An area of 1.0 represents a perfect test; an area of 0.5 represents a test that is no better at predicting clinical response than "flipping a coin". Areas above 0.5 represent increasing accuracy. The accuracy of the length-13 probe set panel in predicting clinical response at Week 6 (AUCROC: 0.520; lower bound of 95% CI: 0.419; p-value=0.740) and at Week 30 (AUCROC: 0.588; lower bound of 95% CI:0.488; pvalue= 0.148) is not significantly greater than 0.5.

End point type	Secondary

End point timeframe:

Week 6 and Week 30

End point values	Biomarker analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	93[3]			
Units: probability				
number (not applicable)				
Week 6	0.52			
Week 30	0.588			

Notes:

[3] - Biomarker analysis set

Statistical analyses

No statistical analyses for this end point

Secondary: The Area Under the Receiver Operating Characteristic Curve of a Subset of the Length-109 Probe set Panel as a Predictor of Clinical Remission at Week 6 and at Week 30

End point title	The Area Under the Receiver Operating Characteristic Curve of a Subset of the Length-109 Probe set Panel as a Predictor of Clinical Remission at Week 6 and at Week 30

End point description:

The area under the Receiver Operating Characteristic curve is a mathematical model used to measure the accuracy of a test. The accuracy of a subset of the length-109 probe set panel (a genetic test administered at screening) is being evaluated in terms of its ability to predict clinical remission. An area of 1.0 represents a perfect test; an area of 0.5 represents a test that is no better at predicting clinical remission than "flipping a coin". Areas above 0.5 represent increasing accuracy. The accuracy of the length-13 probe set panel in predicting clinical remission at Week 6 (AUCROC: 0.558; lower bound of 95% CI: 0.429; p-value=0.462]and at Week 30 (AUCROC: 0.633; lower bound of 95% CI: 0.517; pvalue= 0.059) is not significantly greater than 0.5.

End point type	Secondary

End point timeframe:

Week 6 and Week 30

End point values	Biomarker analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	93[4]			
Units: probability				
number (not applicable)				
Week 6	0.558			
Week 30	0.633			

Notes:

[4] - Biomarker analysis set

Statistical analyses

No statistical analyses for this end point

Secondary: The Area Under the Receiver Operating Characteristic Curve of a Subset of the Length-109 Probe set Panel as a Predictor of Mucosal Healing at Week 30

End point title	The Area Under the Receiver Operating Characteristic Curve of a Subset of the Length-109 Probe set Panel as a Predictor of Mucosal Healing at Week 30

End point description:

The area under the Receiver Operating Characteristic curve is a mathematical model used to measure the accuracy of a test. The accuracy of a subset of the length-109 probe set panel (a genetic test administered at screening) is being evaluated in terms of its ability to predict mucosal healing at Week 30. An area of 1.0 represents a perfect test; an area of 0.5 represents a test that is no better at predicting mucosal healing than "flipping a coin". Areas above 0.5 represent increasing accuracy. The accuracy of the length-13 probe set panel in predicting mucosal healing at Week 30 is norminally significantly greater than 0.5 (AUCROC: 0.671; lower bound of 95% CI: 0.569; p-value=0.006.

End point type	Secondary

End point timeframe:

Week 30

End point values	Biomarker analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	93[5]			
Units: probability				
number (not applicable)	0.671			

Notes:

[5] - Biomarker analysis set

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Screening up to follow-up (week 58)	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups	
Reporting group title	Golimumab Induction Only
Reporting group description: All subjects only received golimumab induction subcutaneous (SC) dose of 200 milligram (mg) at week 0 followed by 100 mg at week 2. No maintenance dose given to subjects in this reporting group.	
Reporting group title	Golimumab induction + 100 mg maintenance
Reporting group description: Subjects received golimumab induction SC dose of 200 mg at week 0 and 100 mg at week 2 followed by SC maintenance dose of golimumab 100 mg at week 6 and every 4 weeks (q4w) thereafter through week 50.	
Reporting group title	Total
Reporting group description: Subjects who received at least 1 dose of study agent.	
Reporting group title	Golimumab induction + 50 mg maintenance
Reporting group description: Subjects received golimumab induction SC dose of 200 mg at week 0 and 100 mg at week 2 followed by SC maintenance dose of golimumab 50 mg at week 6 and every 4 weeks (q4w) thereafter through week 50.	

Serious adverse events	Golimumab Induction Only	Golimumab induction + 100 mg maintenance	Total
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	5 / 76 (6.58%)	11 / 103 (10.68%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 76 (1.32%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	1 / 3 (33.33%)	0 / 76 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 76 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 76 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ulcerative			
subjects affected / exposed	1 / 3 (33.33%)	3 / 76 (3.95%)	7 / 103 (6.80%)
occurrences causally related to treatment / all	0 / 2	1 / 3	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Megacolon			
subjects affected / exposed	0 / 3 (0.00%)	0 / 76 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis Viral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 76 (1.32%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 76 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 76 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypomagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 76 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Golimumab induction + 50 mg maintenance		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 24 (20.83%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iron Deficiency Anaemia			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis Ulcerative			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Megacolon			

subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Gastroenteritis Viral			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypomagnesaemia			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Golimumab Induction Only	Golimumab induction + 100 mg maintenance	Total
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	30 / 76 (39.47%)	45 / 103 (43.69%)
Cardiac disorders			
Sinus Tachycardia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 76 (0.00%)	1 / 103 (0.97%)
occurrences (all)	1	0	1
Nervous system disorders			
Headache			

subjects affected / exposed	0 / 3 (0.00%)	7 / 76 (9.21%)	7 / 103 (6.80%)
occurrences (all)	0	15	15
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	0 / 3 (0.00%)	4 / 76 (5.26%)	4 / 103 (3.88%)
occurrences (all)	0	6	6
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 76 (1.32%)	3 / 103 (2.91%)
occurrences (all)	0	1	3
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	1 / 3 (33.33%)	0 / 76 (0.00%)	1 / 103 (0.97%)
occurrences (all)	1	0	1
Abdominal Pain			
subjects affected / exposed	0 / 3 (0.00%)	4 / 76 (5.26%)	4 / 103 (3.88%)
occurrences (all)	0	4	4
Colitis Ulcerative			
subjects affected / exposed	0 / 3 (0.00%)	16 / 76 (21.05%)	24 / 103 (23.30%)
occurrences (all)	0	16	28
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	2 / 76 (2.63%)	4 / 103 (3.88%)
occurrences (all)	1	2	4
Gastrointestinal Disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 76 (0.00%)	1 / 103 (0.97%)
occurrences (all)	1	0	1
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	4 / 76 (5.26%)	5 / 103 (4.85%)
occurrences (all)	0	4	6
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	4 / 76 (5.26%)	5 / 103 (4.85%)
occurrences (all)	0	4	6
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	4 / 76 (5.26%)	5 / 103 (4.85%)
occurrences (all)	0	4	5
Psychiatric disorders			

Depression			
subjects affected / exposed	1 / 3 (33.33%)	1 / 76 (1.32%)	2 / 103 (1.94%)
occurrences (all)	1	1	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 76 (5.26%)	4 / 103 (3.88%)
occurrences (all)	0	4	4
Infections and infestations			
Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 76 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	0	2
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	10 / 76 (13.16%)	12 / 103 (11.65%)
occurrences (all)	0	13	15

Non-serious adverse events	Golimumab induction + 50 mg maintenance		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 24 (54.17%)		
Cardiac disorders			
Sinus Tachycardia			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	0 / 24 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Gastrointestinal disorders			
Abdominal Discomfort			

subjects affected / exposed occurrences (all) Abdominal Pain subjects affected / exposed occurrences (all) Colitis Ulcerative subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Gastrointestinal Disorder subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0 0 / 24 (0.00%) 0 8 / 24 (33.33%) 12 1 / 24 (4.17%) 1 0 / 24 (0.00%) 0 1 / 24 (4.17%) 2 1 / 24 (4.17%) 2		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1		
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0		
Infections and infestations Respiratory Tract Infection subjects affected / exposed occurrences (all)	2 / 24 (8.33%) 2		

Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	2 / 24 (8.33%) 2		

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.

The 2 maintenance doses (50 mg q4w and 100 mg q4w) were not randomly assigned but followed regional posology guidelines in each country. Therefore, the interpretation of results was based on the total number of subjects treated.

Notes: