Clinical trial results:
Rapidity of onset of response to Adalimumab in luminal Crohn's disease. RAPIDA study.

Summary

EudraCT number	2013-004781-34
Trial protocol	ES
Global end of trial date	23 January 2017

Results information

Result version number	v1 (current)
This version publication date	24 January 2018
First version publication date	24 January 2018

Trial information

Trial identification

Sponsor protocol code	W13-984

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02148718
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co. KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6-4UB
Public contact	Global Medical Services, AbbVie, 001 800-633-9110,
Scientific contact	Maria Belen Garbayo Guijarro, AbbVie, belen.garbayo@abbvie.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	23 January 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 January 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the rapidity of onset of clinical response to adalimumab therapy in patients with luminal Crohn's disease

Protection of trial subjects:

Subject read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 June 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	Spain: 100
Worldwide total number of subjects	100
EEA total number of subjects	100

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)	96
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 100 participants were enrolled in the study; 14 participants did not receive study drug and are excluded from the analyses.

Period 1

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

Arms

Arm title	Adalimumab

Arm description:

Participants received adalimumab for 12 weeks (160 mg at Week 0; 80 mg at week 2; then adalimumab 40 mg every other week starting at Week 4).

Arm type	Experimental
Investigational medicinal product name	adalimumab
Investigational medicinal product code	
Other name	Humira, ABT-D2E7
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab pre-filled syringe, administered by subcutaneous injection

Number of subjects in period 1[1]	Adalimumab
Started	86
Completed	55
Not completed	31
Protocol violation	26
Discontinued study prematurely	5

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Intent to Treat (ITT) population: all enrolled participants who received at least 1 dose of study drug

Baseline characteristics

Reporting groups	
Reporting group title	Adalimumab
Reporting group description:	
Participants received adalimumab for 12 weeks (160 mg at Week 0; 80 mg at week 2; then adalimumab 40 mg every other week starting at Week 4).	

Reporting group values	Adalimumab	Total	
Number of subjects	86	86	
Age categorical Units: Subjects			

Age continuous			
Intent to Treat (ITT) population: all enrolled participants who received at least 1 dose of study drug			
Units: years			
arithmetic mean	37.73		
standard deviation	± 12.16	-	
Gender categorical			
Intent to Treat (ITT) population: all enrolled participants who received at least 1 dose of study drug			
Units: Subjects			
Female	49	49	
Male	37	37	

End points

End points reporting groups

Reporting group title	Adalimumab

Reporting group description:

Participants received adalimumab for 12 weeks (160 mg at Week 0; 80 mg at week 2; then adalimumab 40 mg every other week starting at Week 4).

Primary: Percentage of Participants With Clinical Response at Day 4

End point title	Percentage of Participants With Clinical Response at Day 4[1]

End point description:

Clinical response defined as a decrease of at least 3 points in Harvey-Bradshaw Index (HBI) score. The HBI consists of only clinical parameters (general well-being, abdominal pain, number of liquid stools per day, abdominal mass, and complications): The first 3 items are scored for the previous day. Patients with Crohn's disease who scored 3 or less on the HBI are very likely to be in remission. Patients with a score of 8 to 9 or higher are considered to have severe disease.

End point type	Primary

End point timeframe:

Day 4

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: Descriptive data are summarized for this end point per protocol.

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	86[2]			
Units: percentage of participants				
number (confidence interval 95%)	61.63 (50.51 to 71.92)			

Notes:

[2] - Intent to Treat (ITT) population: all enrolled participants who received ≥ 1 dose of study drug

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Clinical Response at Week 1

End point title	Percentage of Participants With Clinical Response at Week 1

End point description:

Clinical response defined as a decrease of at least 3 points in HBI score. The HBI consists of only clinical parameters (general well-being, abdominal pain, number of liquid stools per day, abdominal mass, and complications): The first 3 items are scored for the previous day. Patients with Crohn's disease who scored 3 or less on the HBI are very likely to be in remission. Patients with a score of 8 to 9 or higher are considered to have severe disease.

End point type	Secondary

End point timeframe:

Week 1

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	86[3]			
Units: percentage of participants				
number (confidence interval 95%)	75.58 (65.13 to 84.20)			

Notes:

[3] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Clinical Remission at Weeks 2 and 4

End point title	Percentage of Participants With Clinical Remission at Weeks 2 and 4

End point description:

Clinical remission defined as HBI < 5. The HBI consists of only clinical parameters (general well-being, abdominal pain, number of liquid stools per day, abdominal mass, and complications): The first 3 items are scored for the previous day. Patients with Crohn's disease who scored 3 or less on the HBI are very likely to be in remission. Patients with a score of 8 to 9 or higher are considered to have severe disease.

End point type	Secondary

End point timeframe:

Weeks 2 and 4

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	86[4]			
Units: percentage of participants				
number (confidence interval 95%)				
Week 2	54.65 (43.55 to 65.42)			
Week 4	62.79 (51.70 to 72.98)			

Notes:

[4] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: European Quality of Life (EuroQol) 5 Dimensions 3 Levels Questionnaire (EQ-5D-3L) Index Score: Change From Baseline to Week 12

End point title	European Quality of Life (EuroQol) 5 Dimensions 3 Levels Questionnaire (EQ-5D-3L) Index Score: Change From Baseline to Week 12

End point description:

The EQ-5D-3L is a standardized instrument for use as a measure of HRQoL and consists of 2 components:
1.The EQ-5D-3L Index Score has five dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with 3 levels of severity for each dimension ('no problems', 'some problems', and 'extreme problems'). The level of severity reported on each of the EQ-5D-3L dimensions determines a unique health state. Health states are converted into a weighted health state index. These weights lie on a scale on which full health has a value of 1 and dead has a value of 0.
2.The EQ-5D visual analog scale (VAS) is a 20-cm scale with endpoints labeled "best imaginable health" and "worst imaginable health" anchored at 100 and 0, respectively.
A positive change represents an improvement in HRQoL. Mean Baseline and mean change from Baseline to Week 12 in the EQ-5D-3L Index Score are presented.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	82[5]			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline	0.62 (± 0.22)			
Change from Baseline to Week 12	0.14 (± 0.25)			

Notes:

[5] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: European Quality of Life (EuroQol) 5 Dimensions 3 Levels Questionnaire (EQ-5D-3L) Visual Analog Scale (VAS): Change From Baseline to Week 12

End point title	European Quality of Life (EuroQol) 5 Dimensions 3 Levels Questionnaire (EQ-5D-3L) Visual Analog Scale (VAS): Change From Baseline to Week 12

End point description:

The EQ-5D-3L is a standardized instrument for use as a measure of HRQoL and consists of 2 components:
1.The EQ-5D-3L Index Score has five dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with 3 levels of severity for each dimension ('no problems', 'some problems', and 'extreme problems'). The level of severity reported on each of the EQ-5D-3L dimensions determines a unique health state. Health states are converted into a weighted health state index. These weights lie on a scale on which full health has a value of 1 and dead has a value of 0.
2.The EQ-5D VAS is a 20-cm scale with endpoints labeled "best imaginable health" and "worst imaginable health" anchored at 100 and 0, respectively.
A positive change represents an improvement in HRQoL. Mean Baseline and mean change from Baseline to Week 12 in the EQ-5D-3L VAS are presented.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	82[6]			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline	55.36 (± 18.52)			
Change from Baseline to Week 12	15.37 (± 21.36)			

Notes:

[6] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Inflammatory Bowel Disease Quality-36 (IBDQ-36) Questionnaire Overall Score: Change From Baseline to Week 12

End point title	Inflammatory Bowel Disease Quality-36 (IBDQ-36) Questionnaire Overall Score: Change From Baseline to Week 12

End point description:

The IBDQ-36 is used to assess the HRQoL related to bowel symptoms. The IBDQ-36 overall score is calculated as the sum of thirty-six items, each scored on a 1 to 7 likert point scale, and ranges from 7 to 252. The highest score indicates the best HRQoL related to bowel symptoms. A positive change in IBDQ-36 overall score indicates an improvement in HRQoL due to inflammatory bowel disease. Mean Baseline and mean change from Baseline to Week 12 in the EQ-5D-3L VAS are presented.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	78[7]			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline	145.1 (± 35.83)			
Change from Baseline to Week 12	44.72 (± 37.98)			

Notes:

[7] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Fatigue Impact Scale for Daily Use (D-FIS): Change From Baseline to Week 12

End point title	Fatigue Impact Scale for Daily Use (D-FIS): Change From Baseline to Week 12

End point description:

The D-FIS is used to measure the impact of fatigue on the daily lives of persons. The D-FIS overall score was calculated as the sum of eight items, each scored on a 0 to 4 point scale, and ranges from 0 to 32. A higher score indicates a higher impact of fatigue on daily life. A negative change in D-FIS Overall Score means an improvement in HRQoL due to fatigue. Mean Baseline and mean change from Baseline to Week 12 are presented.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	79[8]			
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline	14.45 (± 8.53)			
Change from Baseline to Week 12	-4.69 (± 8.44)			

Notes:

[8] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in Analytic Markers of Inflammation: Hemoglobin

End point title	Change From Baseline to Week 12 in Analytic Markers of Inflammation: Hemoglobin

End point description:

Analytic markers of inflammation are hemogram (hemoglobin, hematocrit, leukocytes, neutrophils, lymphocytes, monocytes, eosinophils, basophils, and platelets), erythrocytes sedimentation rate (ESR), C-reactive protein (CRP), fecal calprotectin, and coagulation (activated partial thromboplastin time [aPTT], international normalized ratio [INR], and fibrinogen). Mean Baseline and mean change from Baseline to Week 12 are presented. N=number of subjects with evaluable data at given time point.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	84[9]			
Units: dg/dL				
arithmetic mean (standard deviation)				
Baseline (N-84)	13.01 (± 1.40)			
Change from Baseline to Week 12 (N=79)	0.27 (± 0.97)			

Notes:

[9] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in Analytic Markers of Inflammation: Hematocrit

End point title	Change From Baseline to Week 12 in Analytic Markers of Inflammation: Hematocrit

End point description:

Analytic markers of inflammation are hemogram (hemoglobin, hematocrit, leukocytes, neutrophils, lymphocytes, monocytes, eosinophils, basophils, and platelets), erythrocytes, ESR, CRP, fecal calprotectin, and coagulation (aPTT, INR, and fibrinogen). Mean Baseline and mean change from Baseline to Week 12 for each parameter are presented. N=number of subjects with evaluable data at given time point.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	84[10]			
Units: % volume				
arithmetic mean (standard deviation)				
Baseline (N=84)	39.47 (± 3.99)			
Change from Baseline to Week 12 (N=79)	0.86 (± 2.79)			

Notes:

[10] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in Analytic Markers of Inflammation: Leukocytes, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, and Platelets

End point title	Change From Baseline to Week 12 in Analytic Markers of Inflammation: Leukocytes, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, and Platelets

End point description:

Analytic markers of inflammation are hemogram (hemoglobin, hematocrit, leukocytes, neutrophils, lymphocytes, monocytes, eosinophils, basophils, and platelets), erythrocytes, ESR, CRP, fecal calprotectin, and coagulation (aPTT, INR, and fibrinogen). Mean Baseline and mean change from Baseline to Week 12 for each parameter are presented. N=number of subjects with evaluable data at given time point.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	84[11]			
Units: cellsx10^3/uL				
arithmetic mean (standard deviation)				
Leukocytes Baseline (N=84)	8.11 (± 3.23)			
Leukocytes Change from Baseline to Week 12 (N=79)	-1.62 (± 2.87)			
Neutrophils Baseline (N=84)	5.61 (± 2.86)			
Neutrophils Change from Baseline to Week 12 (N=79	-1.99 (± 2.87)			
Lymphocytes Baseline (N=84)	1.80 (± 0.94)			
Lymphocytes Change from Baseline to Week 12 (N=79)	0.39 (± 0.76)			
Monocytes Baseline (N=84)	0.50 (± 0.25)			
Monocytes Change from Baseline to Week 12 (N=79)	-0.009 (± 0.219)			
Eosinophils Baseline (N=84)	0.17 (± 0.15)			
Eosinophils Change from Baseline to Week 12 (N=79)	-0.010 (± 0.095)			
Basophils Baseline (N=84)	0.02 (± 0.02)			
Basophils Change from Baseline to Week 12 (N=79)	0.003 (± 0.033)			
Platelets Baseline (N=84)	316.1 (± 90.1)			
Platelets Change from Baseline to Week 12 (N=79)	-40.4 (± 76.4)			

Notes:

[11] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in Analytic Markers of Inflammation: Sedimentation Rate (ESR)

End point title	Change From Baseline to Week 12 in Analytic Markers of Inflammation: Sedimentation Rate (ESR)

End point description:

Analytic markers of inflammation are hemogram (hemoglobin, hematocrit, leukocytes, neutrophils, lymphocytes, monocytes, eosinophils, basophils, and platelets), erythrocytes, ESR, CRP, fecal calprotectin, and coagulation (aPTT, INR, and fibrinogen). Mean Baseline and mean change from Baseline to Week 12 for each parameter are presented. N=number of subjects with evaluable data at given time point.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	84[12]			
Units: mm				
arithmetic mean (standard deviation)				
Baseline (N=84)	19.49 (± 18.38)			
Change from Baseline to Week 12 (N=79)	-7.48 (± 14.26)			

Notes:

[12] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in Analytic Markers of Inflammation: C-reactive Protein (CRP)

End point title	Change From Baseline to Week 12 in Analytic Markers of Inflammation: C-reactive Protein (CRP)

End point description:

Analytic markers of inflammation are hemogram (hemoglobin, hematocrit, leukocytes, neutrophils, lymphocytes, monocytes, eosinophils, basophils, and platelets), erythrocytes, ESR, CRP, fecal calprotectin, and coagulation (aPTT, INR, and fibrinogen). Mean Baseline and mean change from Baseline to Week 12 for each parameter are presented. N=number of subjects with evaluable data at given time point.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	85[13]			
Units: U/L				
arithmetic mean (standard deviation)				
Baseline (N=85)	11.06 (± 16.2)			
Change from Baseline to Week 12 (N=80)	-7.61 (± 16.4)			

Notes:

[13] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in Analytic Markers of Inflammation:

Fecal Calprotectin

End point title	Change From Baseline to Week 12 in Analytic Markers of Inflammation: Fecal Calprotectin

End point description:

Analytic markers of inflammation are hemogram (hemoglobin, hematocrit, leukocytes, neutrophils, lymphocytes, monocytes, eosinophils, basophils, and platelets), erythrocytes, ESR, CRP, fecal calprotectin, and coagulation (aPTT, INR, and fibrinogen). Mean Baseline and mean change from Baseline to Week 12 for each parameter are presented. N=number of subjects with evaluable data at given time point.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	74[14]			
Units: mg/kg				
arithmetic mean (standard deviation)				
Baseline (N=74)	1550.4 (± 2798.4)			
Baseline to Week 12 (N=61)	-1043.8 (± 2895.3)			

Notes:

[14] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in Analytic Markers of Inflammation: Activated Partial Thromboplastin Time (aPTT)

End point title	Change From Baseline to Week 12 in Analytic Markers of Inflammation: Activated Partial Thromboplastin Time (aPTT)

End point description:

Analytic markers of inflammation are hemogram (hemoglobin, hematocrit, leukocytes, neutrophils, lymphocytes, monocytes, eosinophils, basophils, and platelets), erythrocytes, ESR, CRP, fecal calprotectin, and coagulation (aPTT, INR, and fibrinogen). Mean Baseline and mean change from Baseline to Week 12 for each parameter are presented. N=number of subjects with evaluable data at given time point.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	85[15]			
Units: sec				
arithmetic mean (standard deviation)				
Baseline (N=85)	30.58 (± 3.89)			
Change from Baseline to Week 12 (N=79)	0.76 (± 3.97)			

Notes:

[15] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in Analytic Markers of Inflammation: International Normalized Ratio (INR)

End point title	Change From Baseline to Week 12 in Analytic Markers of Inflammation: International Normalized Ratio (INR)

End point description:

Analytic markers of inflammation are hemogram (hemoglobin, hematocrit, leukocytes, neutrophils, lymphocytes, monocytes, eosinophils, basophils, and platelets), erythrocytes, ESR, CRP, fecal calprotectin, and coagulation (aPTT, INR, and fibrinogen). Mean Baseline and mean change from Baseline to Week 12 for each parameter are presented. N=number of subjects with evaluable data at given time point.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	85[16]			
Units: ratio				
arithmetic mean (standard deviation)				
Baseline (N=85)	1.05 (± 0.06)			
Change from Baseline to Week 12 (N=79)	0.02 (± 0.07)			

Notes:

[16] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in Analytic Markers of Inflammation: Fibrinogen

End point title	Change From Baseline to Week 12 in Analytic Markers of Inflammation: Fibrinogen

End point description:

Analytic markers of inflammation are hemogram (hemoglobin, hematocrit, leukocytes, neutrophils,

lymphocytes, monocytes, eosinophils, basophils, and platelets), erythrocytes, ESR, CRP, fecal calprotectin, and coagulation (aPTT, INR, and fibrinogen). Mean Baseline and mean change from Baseline to Week 12 for each parameter are presented. N=number of subjects with evaluable data at given time point.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	85[17]			
Units: mg/dL				
arithmetic mean (standard deviation)				
Baseline (N=85)	374.5 (± 68.17)			
Change from Baseline to Week 12 (N=79)	-43.6 (± 65.7)			

Notes:

[17] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Clinical Response at Day 4 or Week 12 and Clinical Remission at Week 12

End point title	Percentage of Participants With Clinical Response at Day 4 or Week 12 and Clinical Remission at Week 12

End point description:

The percentage of participants with clinical response (defined as decrease of at least 3 points in HBI score) at Day 4 or Week 1 and clinical remission (defined as a HBI < 5) at Week 12.

End point type	Secondary

End point timeframe:

Up to Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	86[18]			
Units: percentage of participants				
number (not applicable)	58.90			

Notes:

[18] - ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 12 in Analytic Markers of Inflammation: Erythrocytes

End point title	Change From Baseline to Week 12 in Analytic Markers of Inflammation: Erythrocytes

End point description:

Analytic markers of inflammation are hemogram (hemoglobin, hematocrit, leukocytes, neutrophils, lymphocytes, monocytes, eosinophils, basophils, and platelets), erythrocytes, ESR, CRP, fecal calprotectin, and coagulation (aPTT, INR, and fibrinogen). Mean Baseline and mean change from Baseline to Week 12 for each parameter are presented. N=number of subjects with evaluable data at given time point.

End point type	Secondary

End point timeframe:

Baseline (Week 0) and Week 12

End point values	Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	84[19]			
Units: cellsx10^6/uL				
arithmetic mean (standard deviation)				
Baseline (N=84)	4.37 (± 0.51)			
Change from Baseline to Week 12 (N=79)	0.052 (± 0.308)			

Notes:

[19] - All participants in the ITT population with evaluable data

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events (TEAEs) and serious adverse events (TESAEs) were collected from the time of study drug administration until 70 days after the last dose of study drug (up to 20 weeks).

Adverse event reporting additional description:

TEAEs and TESAEs are defined as any AE or SAE with an onset date after the first dose of study drug until 70 days after the last dose of study drug and were collected whether elicited or spontaneously reported by the participant.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Adalimumab

Reporting group description:

Participants received adalimumab for 12 weeks (160 mg at Week 0; 80 mg at week 2; then adalimumab 40 mg every other week starting at Week 4).

Serious adverse events	Adalimumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 86 (2.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Adalimumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	35 / 86 (40.70%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Fatigue			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
General physical health deterioration			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Investigations			

Blood triglycerides increased subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Transaminases increased subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Weight decreased subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Migraine subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Eye disorders Eyelid disorder subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Lacrimation increased subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Presbyopia subjects affected / exposed occurrences (all)	1 / 86 (1.16%) 1		
Gastrointestinal disorders Abdominal mass			

subjects affected / exposed	3 / 86 (3.49%)		
occurrences (all)	5		
Abdominal pain			
subjects affected / exposed	3 / 86 (3.49%)		
occurrences (all)	3		
Aphthous ulcer			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Crohn's disease			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	3 / 86 (3.49%)		
occurrences (all)	3		
Haemorrhoids			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Subileus			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	4 / 86 (4.65%)		
occurrences (all)	6		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Eczema			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Psoriasis			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	4		

Rash			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	2		
Skin lesion			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 86 (3.49%)		
occurrences (all)	4		
Arthritis			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Flank pain			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Muscular weakness			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Sacroiliitis			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Folliculitis			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Herpes virus infection			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	3		
Influenza			

subjects affected / exposed	4 / 86 (4.65%)		
occurrences (all)	4		
Nasopharyngitis			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Pharyngitis			
subjects affected / exposed	3 / 86 (3.49%)		
occurrences (all)	3		
Pharyngotonsillitis			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Rash pustular			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Respiratory tract infection			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	2		
Rotavirus infection			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Tooth infection			
subjects affected / exposed	1 / 86 (1.16%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	2 / 86 (2.33%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported