Clinical trial results:
A Multi-Center, Randomized, Double-blind, Placebo-controlled Study of Adalimumab for the Maintenance of Clinical Remission in Japanese Subjects with Crohn's Disease

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2014-004531-39
Trial protocol	Outside EU/EEA
Global end of trial date	26 November 2010

Results information

Result version number	v2 (current)
This version publication date	17 June 2016
First version publication date	13 June 2015
Version creation reason	• Correction of full data set potential timestamp issues

Trial information

Trial identification

Sponsor protocol code	M06-837

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00445432
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie
Sponsor organisation address	1 North Waukegan Road, North Chicago, IL, United States, 60064
Public contact	Global Medical Information, AbbVie, 001 800-633-9110,
Scientific contact	Global Medical Information, AbbVie, 001 800-633-9110,

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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 November 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 November 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the efficacy and safety of adalimumab for the maintenance of clinical remission in Japanese subjects with Crohn's disease (CD).

Protection of trial subjects:

Prior to any study-related screening procedures being performed on the subject, the informed consent statement was reviewed and signed and dated by the subject and/or parent or legal guardian (if the subject was < 20 years old) and the person who administered the informed consent. If clinical trial support staff gave additional explanations, he/she also signed and date the informed consent statement.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 March 2007
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	Japan: 83
Worldwide total number of subjects	83
EEA total number of subjects	0

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)	2
Adults (18-64 years)	81
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All participants who completed lead-in adalimumab induction therapy study (M04-729 [NCT00445939]) were eligible.

Pre-assignment

Screening details:

Participants who rolled over into this study received either double-blind (DB) treatment (adalimumab or placebo; responders (decrease in Crohn's Disease Activity Index [CDAI] ≥70 points from lead-in baseline score [CR-70 response] by Week 4 of M14-729) or open-label (OL) treatment (adalimumab; non-responders by Week 4 of M14-729).

Period 1

Period 1 title	Through Week 52 of NCT00445432 (M06-837)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Assessor

Blinding implementation details:

Participants who had CR-70 response at Week 4 of the induction study (study M04-729 [NCT00445939]) were randomized into 1 of 2 treatment groups (DB adalimumab 40 mg every other week or DB adalimumab placebo every other week) using 2 stratification factors - CDAI category (CDAI less than 150 and CDAI 150 or higher) and presence/absence of fistula at Week 0 of this study.

Arms

Are arms mutually exclusive?	Yes
Arm title	DB Adalimumab 40 mg Eow

Arm description:

Double-blind adalimumab 40 mg every other week

Arm type	Experimental
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	Humira, D2E7
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous injection of 40 mg adalimumab (0.8 mL/injection) every other week (eow)

Arm title	OL Adalimumab 40 mg Eow

Arm description:

Open-label adalimumab 40 mg every other week (eow)

Arm type	Experimental
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	Humira, D2E7
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous injection of 40 mg adalimumab (0.8 mL/injection) every other week (eow)

Arm title	DB Placebo Eow

Arm description:

Double-blind adalimumab placebo every other week (eow)

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

Dosage and administration details:

Subcutaneous injection of placebo (0.8 mL/injection) every other week (eow)

Number of subjects in period 1[1]	DB Adalimumab 40 mg Eow	OL Adalimumab 40 mg Eow	DB Placebo Eow
Started	25	32	25
Completed	10	21	2
Not completed	15	11	23
Consent withdrawn by subject	-	2	-
Not specified	-	2	1
Adverse event	1	7	2
Moved to open-label	14	-	20

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: Any Adalimumab includes all subjects who had at least one dose of adalimumab during study M06-837: 32 subjects were randomized to receive OL adalimumab, 25 subjects were randomized to DB adalimumab, and 24 subjects were randomized to receive DB placebo and switched to OL adalimumab (3 subjects discontinued while receiving DB placebo and never received any adalimumab).

Period 2

Period 2 title	148 Weeks of Adalimumab Treatment
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Any Adalimumab

Arm description:

All participants in NCT00445432 (Study M06-837) who received at least 1 dose of adalimumab 40 mg every other week (double-blind or open-label).

Arm type	Experimental
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	Humira, D2E7
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous injection of 40 mg adalimumab (0.8 mL/injection) every other week (eow)

Number of subjects in period 2[2]	Any Adalimumab
Started	32
Completed	35
Not completed	44
Consent withdrawn by subject	3
Not specified	9
Adverse event	32
Joined	47
Randomized to DB placebo-switched to OL adalimumab	22
Randomized to DB adalimumab	25

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: One subject was randomized but did not receive study drug; the subject was excluded from efficacy analyses.

Baseline characteristics

Reporting groups	
Reporting group title	DB Adalimumab 40 mg Eow
Reporting group description:	
Double-blind adalimumab 40 mg every other week	
Reporting group title	OL Adalimumab 40 mg Eow
Reporting group description:	
Open-label adalimumab 40 mg every other week (eow)	
Reporting group title	DB Placebo Eow
Reporting group description:	
Double-blind adalimumab placebo every other week (eow)	

Reporting group values	DB Adalimumab 40 mg Eow	OL Adalimumab 40 mg Eow	DB Placebo Eow
Number of subjects	25	32	25
Age categorical Units: Subjects			
<=18 years	0	3	2
Between 18 and 65 years	25	29	23
>=65 years	0	0	0
Age continuous Units:			
	31.6 ± 7.171	30.75 ± 8.359	30.8 ± 10.939
Gender categorical Units: Subjects			
Female	9	14	10
Male	16	18	15

Reporting group values	Total		
Number of subjects	82		
Age categorical Units: Subjects			
<=18 years	5		
Between 18 and 65 years	77		
>=65 years	0		
Age continuous Units:			
	-		
Gender categorical Units: Subjects			
Female	33		
Male	49		

End points

End points reporting groups

Reporting group title	DB Adalimumab 40 mg Eow
Reporting group description:	
Double-blind adalimumab 40 mg every other week	
Reporting group title	OL Adalimumab 40 mg Eow
Reporting group description:	
Open-label adalimumab 40 mg every other week (eow)	
Reporting group title	DB Placebo Eow
Reporting group description:	
Double-blind adalimumab placebo every other week (eow)	
Reporting group title	Any Adalimumab
Reporting group description:	
All participants in NCT00445432 (Study M06-837) who received at least 1 dose of adalimumab 40 mg every other week (double-blind or open-label).	

Primary: Number of Participants Who Had Clinical Remission at Week 52 of Double-blind Treatment

End point title	Number of Participants Who Had Clinical Remission at Week 52 of Double-blind Treatment[1][2]
End point description:	
Clinical remission=Crohn's Disease Activity Index (CDAI) < 150; number of soft stools, abdominal pain, general well-being, presence of 6 signs (arthritis/arthralgia; iritis/uveitis; erythema nodosum/pyoderma gangrenosum/aphthous stomatitis; fissure, abscess, anal fistula; other cutaneous fistula; fever over 100 degrees), taking medication for diarrhea, abdominal mass, hematocrit, and weight loss are documented during 1-week assessment period. CDAI total score is >= 0 and without upper limit. Low score=less severe CD activity. Decrease indicates improvement. Modified Full Analysis Set (mFAS), defined as participants who had received adalimumab (not placebo) during the adalimumab induction study and who received at least 1 dose of DB study drug during this study. Nonresponder imputation (NRI) (clinical remission not achieved) was used for missing data.	
End point type	Primary
End point timeframe:	
Week 52 of double-blind treatment	

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.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The primary efficacy end point was assessed only in subjects receiving double-blind treatment.

End point values	DB Adalimumab 40 mg Eow	DB Placebo Eow		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	22		
Units: Participants				
number (not applicable)	8	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Who Had Clinical Response-70 (CR-70; a Decrease in Crohn's Disease Activity Index of at Least 70 Points From Lead-in Study [NCT00445939] Baseline Score) at Week 52 of Double-blind Treatment

End point title	Number of Participants Who Had Clinical Response-70 (CR-70; a Decrease in Crohn's Disease Activity Index of at Least 70 Points From Lead-in Study [NCT00445939] Baseline Score) at Week 52 of Double-blind Treatment

End point description:

Crohn's Disease Activity Index (CDAI) documents number of soft stools, abdominal pain, general well-being, presence of 6 signs (arthritis/arthralgia; iritis/uveitis; erythema nodosum/pyoderma gangrenosum/aphthous stomatitis; fissure, abscess, anal fistula; other cutaneous fistula; fever over 100 degrees), taking medication for diarrhea, abdominal mass, hematocrit, and weight loss during a 1-week assessment period. CDAI has a total score >= 0 and without upper limit. Low score=less severe CD activity. Decrease in score indicates improvement. OL efficacy set (assigned to OL treatment at Week 0, received >= 1 dose of OL study drug) and mFAS (participants who had received adalimumab [not placebo] during adalimumab induction study and who received >= 1 dose of DB study drug during this study). NRI (CR-70 not achieved) used for DB treatments; last observation carried forward (LOCF) for OL treatment.

End point type	Secondary

End point timeframe:

Week 52 of double-blind treatment

End point values	DB Adalimumab 40 mg Eow	OL Adalimumab 40 mg Eow	DB Placebo Eow	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	21	32	22	
Units: Participants				
number (not applicable)	9	10	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Who Had Clinical Response-100 (CR-100; a Decrease in Crohn's Disease Activity Index of at Least 100 Points From Lead-in Study [NCT00445939] Baseline Score) at Week 52 of Double-blind Treatment

End point title	Number of Participants Who Had Clinical Response-100 (CR-100; a Decrease in Crohn's Disease Activity Index of at Least 100 Points From Lead-in Study [NCT00445939] Baseline Score) at Week 52 of Double-blind Treatment

End point description:

Crohn's Disease Activity Index (CDAI) documents number of soft stools, abdominal pain, general well-being, presence of 6 signs (arthritis/arthralgia; iritis/uveitis; erythema nodosum/pyoderma gangrenosum/aphthous stomatitis; fissure, abscess, anal fistula; other cutaneous fistula; fever over 100 degrees), taking medication for diarrhea, abdominal mass, hematocrit, and weight loss during a 1-week assessment period. CDAI has a total score >= 0 and without upper limit. Low score=less severe CD activity. Decrease in score indicates improvement. OL efficacy set (assigned to OL treatment at Week 0, received >= 1 dose of OL study drug) and mFAS (participants who had received adalimumab (not placebo) during adalimumab induction study and who received >= 1 dose of DB study drug during this

study). NRI (CR-100 not achieved) used for missing data for DB treatments; LOCF for OL treatment.

End point type	Secondary

End point timeframe:

Week 52 of double-blind treatment

End point values	DB Adalimumab 40 mg Eow	OL Adalimumab 40 mg Eow	DB Placebo Eow	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	21	32	22	
Units: Participants				
number (not applicable)	8	8	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Crohn's Disease Activity Index From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment

End point title	Change in Crohn's Disease Activity Index From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment[3]

End point description:

Crohn's Disease Activity Index (CDAI) is a measure of disease severity. Number of soft stools, abdominal pain, general well-being, presence of 6 signs (arthritis/arthralgia; iritis/uveitis; erythema nodosum/pyoderma gangrenosum/aphthous stomatitis; fissure, abscess, anal fistula; other cutaneous fistula; fever over 100 degrees), taking medication for diarrhea, abdominal mass, hematocrit, and weight loss are documented during 1-week assessment period. CDAI has a total score >= 0 and without upper limit. Low score=less severe CD activity. Decrease in score indicates improvement. Modified Full Analysis Set (mFAS), defined as participants who had received adalimumab (not placebo) during the adalimumab induction study and who received at least 1 dose of DB study drug during this study. LOCF used for missing data.

End point type	Secondary

End point timeframe:

Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The secondary efficacy end point was assessed only in subjects receiving double-blind treatment.

End point values	DB Adalimumab 40 mg Eow	DB Placebo Eow		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	22		
Units: units on a scale				
arithmetic mean (standard deviation)	-83.7 (± 110.26)	-9.1 (± 110.41)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Who Had Clinical Remission at Week 52 of Open-label Treatment

End point title	Number of Participants Who Had Clinical Remission at Week 52 of Open-label Treatment[4]

End point description:

Clinical remission=Crohn's Disease Activity Index (CDAI) < 150; number of soft stools, abdominal pain, general well-being, presence of 6 signs (arthritis/arthralgia; iritis/uveitis; erythema nodosum/pyoderma gangrenosum/aphthous stomatitis; fissure, abscess, anal fistula; other cutaneous fistula; fever over 100 degrees), taking medication for diarrhea, abdominal mass, hematocrit, and weight loss are documented during 1-week assessment period. CDAI total score is >= 0 and without upper limit. Low score=less severe CD activity. Decrease in score indicates improvement. OL efficacy set (assigned to OL treatment at Week 0, received >= 1 dose of OL study drug). LOCF used for missing data.

End point type	Secondary

End point timeframe:

Week 52 of open-label treatment

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Primary efficacy end point was assessed in subjects receiving double-blind treatment.

End point values	OL Adalimumab 40 mg Eow			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
number (not applicable)	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in International Organization for the Study of Inflammatory Bowel Disease (IOIBD) Score From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment

End point title	Change in International Organization for the Study of Inflammatory Bowel Disease (IOIBD) Score From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment[5]

End point description:

The International Organization for the Study of Inflammatory Bowel Disease (IOIBD) score is an indicator of the activity of Crohn's disease. It measures absence (score of 0) or presence (score of 1) of abdominal pain, diarrhea or bloody stools more than 6 times per day, anal lesion, anal fistula, other complication, abdominal mass, weight loss, fever above 38 degrees Centigrade, abdominal tenderness,

and blood pigment below 10 g/dL. Total possible score=0 to 10; low score=less disease activity. Decrease in score indicates alleviation of the disease; increase indicates aggravation of disease. Modified Full Analysis Set (mFAS), defined as participants who had received adalimumab (not placebo) during the adalimumab induction study and who received at least 1 dose of DB study drug during this study. LOCF used for missing data.

End point type	Secondary

End point timeframe:

Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The secondary efficacy end point was assessed only in subjects receiving double-blind treatment.

End point values	DB Adalimumab 40 mg Eow	DB Placebo Eow		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	22		
Units: units on a scale				
arithmetic mean (standard deviation)	-0.8 (± 1.89)	-0.2 (± 1.34)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Inflammatory Bowel Disease Questionnaire (IBDQ) From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment

End point title	Change in Inflammatory Bowel Disease Questionnaire (IBDQ) From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment[6]

End point description:

IBDQ is a validated disease−specific instrument that assesses the impact of IBD on patient quality of life during a 2−week recall period. It has 32 questions about bowel function and related symptoms, and their social and emotional impact. For each item, participants select 1 of 7 responses. 1=poor quality of life (e.g., feeling of fatigue "all of the time") and 7=good quality (e.g., feeling of fatigue "none of the time"). Scoring range = 32 to 224. Higher scores indicate better quality of life; increases in IBDQ = improved overall quality of life. Modified Full Analysis Set (mFAS), defined as participants who had received adalimumab (not placebo) during the adalimumab induction study and who received at least 1 dose of DB study drug during this study. LOCF used for missing data.

End point type	Secondary

End point timeframe:

Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The secondary efficacy end point was assessed only in subjects receiving double-blind treatment.

End point values	DB Adalimumab 40 mg Eow	DB Placebo Eow		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	14		
Units: units on a scale				
arithmetic mean (standard deviation)	27.8 (± 32.44)	1.8 (± 35.42)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Physical Component of the Short Form-36 Health Survey From Baseline of the Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment

End point title	Change in Physical Component of the Short Form-36 Health Survey From Baseline of the Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment[7]

End point description:

The Short-Form-36 (SF-36) Health Survey is a comprehensive quality of life scale. An increase in SF-36 score indicates alleviation of the disease and a decrease in score indicates aggravation of disease. The physical component reflects activity level, activity limitations, pain, and rating of one's health. Score on the physical component ranges from 0 (poorest health) to 100 (best health). Modified Full Analysis Set (mFAS), defined as participants who had received adalimumab (not placebo) during the adalimumab induction study and who received at least 1 dose of DB study drug during this study. LOCF used for missing data.

End point type	Secondary

End point timeframe:

Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The secondary efficacy end point was assessed only in subjects receiving double-blind treatment.

End point values	DB Adalimumab 40 mg Eow	DB Placebo Eow		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	14		
Units: units on a scale				
arithmetic mean (standard deviation)	4.4 (± 9.09)	0.2 (± 6.31)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Mental Component of the Short Form-36 Health Survey From Baseline of the Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment

End point title	Change in Mental Component of the Short Form-36 Health Survey From Baseline of the Lead-in Study (NCT00445939) to

	Week 52 of Double-blind Treatment[8]

End point description:

The Short-Form-36 (SF-36) Health Survey is a comprehensive quality of life scale. An increase in SF-36 score indicates alleviation of the disease and a decrease in score indicates aggravation. The mental component reflects energy/vitality, social functioning, limitations, and ratings of one's mental health. Score on mental component ranges from 0 (worst score) to 100 (best score). Modified Full Analysis Set (mFAS), defined as participants who had received adalimumab (not placebo) during the adalimumab induction study and who received at least 1 dose of DB study drug during this study. LOCF used for missing data.

End point type	Secondary

End point timeframe:

Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The secondary efficacy end point was assessed only in subjects receiving double-blind treatment.

End point values	DB Adalimumab 40 mg Eow	DB Placebo Eow		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	14		
Units: units on a scale				
arithmetic mean (standard deviation)	9.6 (± 8.37)	0.3 (± 14.15)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Participants Who Had Clinical Remission at Week 148

End point title	Number of Participants Who Had Clinical Remission at Week 148

End point description:

Clinical remission=Crohn's Disease Activity Index (CDAI) < 150; number of soft stools, abdominal pain, general well-being, presence of 6 signs (arthritis/arthralgia; iritis/uveitis; erythema nodosum/pyoderma gangrenosum/aphthous stomatitis; fissure, abscess, anal fistula; other cutaneous fistula; fever over 100 degrees), taking medication for diarrhea, abdominal mass, hematocrit, and weight loss are documented during 1-week assessment period. CDAI total score is >= 0 and without upper limit. Low score=less severe CD activity. Decrease indicates improvement. Data is reported as observed cases. No imputation technique was used.

End point type	Other pre-specified

End point timeframe:

Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)

End point values	Any Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: participants				
number (not applicable)	21			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Participants Who Had Clinical Response-70 (CR-70; a Decrease in Crohn's Disease Activity Index of at Least 70 Points from Lead-in Study [NCT00445939] Baseline score) at Week 148

End point title	Number of Participants Who Had Clinical Response-70 (CR-70; a Decrease in Crohn's Disease Activity Index of at Least 70 Points from Lead-in Study [NCT00445939] Baseline score) at Week 148

End point description:

Crohn's Disease Activity Index (CDAI) documents number of soft stools, abdominal pain, general well-being, presence of 6 signs (arthritis/arthralgia; iritis/uveitis; erythema nodosum/pyoderma gangrenosum/aphthous stomatitis; fissure, abscess, anal fistula; other cutaneous fistula; fever over 100 degrees), taking medication for diarrhea, abdominal mass, hematocrit, and weight loss during a 1-week assessment period. CDAI has a total score >= 0 and without upper limit. Low score=less severe CD activity. Decrease in score indicates improvement. Data is reported as observed cases. No imputation technique was used.

End point type	Other pre-specified

End point timeframe:

Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)

End point values	Any Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: participants				
number (not applicable)	28			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Participants Who Had Clinical Response-100 (CR-100; a Decrease in Crohn's Disease Activity Index of at Least 100 Points from Lead-in Study [NCT00445939] Baseline Score) at Week 148

End point title	Number of Participants Who Had Clinical Response-100 (CR-100; a Decrease in Crohn's Disease Activity Index of at Least 100 Points from Lead-in Study [NCT00445939] Baseline Score) at Week 148

End point description:

Crohn's Disease Activity Index (CDAI) documents number of soft stools, abdominal pain, general well-being, presence of 6 signs (arthritis/arthralgia; iritis/uveitis; erythema nodosum/pyoderma gangrenosum/aphthous stomatitis; fissure, abscess, anal fistula; other cutaneous fistula; fever over 100 degrees), taking medication for diarrhea, abdominal mass, hematocrit, and weight loss during a 1-week assessment period. CDAI has a total score >= 0 and without upper limit. Low score=less severe CD activity. Decrease in score indicates improvement. Data is reported as observed cases. No imputation technique was used.

End point type	Other pre-specified

End point timeframe:

Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)

End point values	Any Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: participants				
number (not applicable)	26			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change in Crohn's Disease Activity Index from Baseline of Lead-in Study (NCT00445939) to Week 148

End point title	Change in Crohn's Disease Activity Index from Baseline of Lead-in Study (NCT00445939) to Week 148

End point description:

Crohn's Disease Activity Index (CDAI) is a measure of disease severity. Number of soft stools, abdominal pain, general well-being, presence of 6 signs (arthritis/arthralgia; iritis/uveitis; erythema nodosum/pyoderma gangrenosum/apthous stomatitis; fissure, abscess, anal fistula; other cutaneous fistula; fever over 100 degrees), taking medication for diarrhea, abdominal mass, hematocrit, and weight loss are documented during 1-week assessment period. CDAI has a total score >=0 and without upper limit. Low score=less severe CD activity. Decrease in score indicates improvement. Data is reported as observed cases. No imputation technique was used.

End point type	Other pre-specified

End point timeframe:

Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)

End point values	Any Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: units on a scale				
arithmetic mean (standard deviation)	-143 (± 102.49)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change in International Organization for the Study of Inflammatory Bowel Disease (IOIBD) Score from Baseline of Lead-in Study (NCT00445939) to Week 148

End point title	Change in International Organization for the Study of Inflammatory Bowel Disease (IOIBD) Score from Baseline of Lead-in Study (NCT00445939) to Week 148

End point description:

The International Organization for the Study of Inflammatory Bowel Disease (IOIBD) score is an indicator of the activity of Crohn's disease. It measures absence (score of 0) or presence (score of 1) of abdominal pain, diarrhea or bloody stools more than 6 times per day, anal lesion, anal fistula, other complication, abdominal mass, weight loss, fever above 38 degrees Centigrade, abdominal tenderness, and blood pigment below 10 g/dL. Total possible score=0 to 10; low score=less disease activity. Decrease in score indicates alleviation of the disease; increase indicates aggravation of disease. Data is reported as observed cases. No imputation technique was used.

End point type	Other pre-specified

End point timeframe:

Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)

End point values	Any Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	35			
Units: units on a scale				
arithmetic mean (standard deviation)	-1.7 (± 1.41)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change in Inflammatory Bowel Disease Questionnaire (IBDQ) from Baseline of Lead-in Study (NCT00445939) to Week 148

End point title	Change in Inflammatory Bowel Disease Questionnaire (IBDQ) from Baseline of Lead-in Study (NCT00445939) to Week 148

End point description:

IBDQ is a validated disease-specific instrument that assesses the impact of IBD on patient quality of life during a 2-week recall period with 32 questions about bowel function and related symptoms & their social/emotional impact. Per item, participants select 1 of 7 responses (1=poor quality of life [e.g., feeling of fatigue "all of the time"]; 7=good quality [e.g., feeling of fatigue "none of the time"]). Scoring range=32 to 224. Higher scores indicate better quality of life; increases in IBDQ=improved overall quality of life. Data is reported as observed cases. No imputation technique was used.

End point type	Other pre-specified

End point timeframe:

Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)

End point values	Any Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: units on a scale				
arithmetic mean (standard deviation)	27.2 (± 31.22)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change in Physical Component of the Short Form-36 Health Survey from Baseline of the Lead-in Study (NCT00445939) to Week 148

End point title	Change in Physical Component of the Short Form-36 Health Survey from Baseline of the Lead-in Study (NCT00445939) to Week 148

End point description:

The Short Form-36 (SF-36) Health Survey is a comprehensive quality of life scale. An increase in SF-36 score indicates alleviation of the disease and a decrease in score indicates aggravation of disease. The physical component reflects activity level, activity limitations, pain, and rating of one's health. Score on the physical component ranges from 0 to 100, with 0=Poorest Health and 100=Best Health. Data is reported as observed cases. No imputation technique was used.

End point type	Other pre-specified

End point timeframe:

Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)

End point values	Any Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: units on a scale				
arithmetic mean (standard deviation)	5.44 (± 7.245)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change in Mental Component of the Short Form-36 Health

Survey from Baseline of the Lead-in Study (NCT00445939) to Week 148

End point title	Change in Mental Component of the Short Form-36 Health Survey from Baseline of the Lead-in Study (NCT00445939) to Week 148

End point description:

The Short Form-36 (SF-36) Health Survey is a comprehensive quality of life scale. An increase in SF-36 indicates alleviation of the disease and a decrease in score indicates aggravation. The mental component reflects energy/vitality, social functioning, limitations, and ratings of one's mental health. Score on mental component ranges from 0 (worst score) to 100 (best score). Data is reported as observed cases. No imputation technique was used.

End point type	Other pre-specified

End point timeframe:

Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)

End point values	Any Adalimumab			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: units on a scale				
arithmetic mean (standard deviation)	6.44 (± 11.173)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

52 weeks for the double-blind (DB) treatments (adalimumab and placebo) and for the open-label adalimumab treatment. Overall study (maximum adalimumab treatment of 184 weeks plus 70-day follow-up period) for the Any Adalimumab group.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	9.1

Reporting groups

Reporting group title	DB Adalimumab 40 mg Eow

Reporting group description:

Double-blind adalimumab 40 mg every other week (eow)

Reporting group title	DB Placebo Eow

Reporting group description:

Double-blind adalimumab placebo every other week (eow)

Reporting group title	OL Adalimumab 40 mg Eow

Reporting group description:

Open-label adalimumab 40 mg every other week (eow)

Reporting group title	Any Adalimumab

Reporting group description:

All participants in this study who received at least 1 dose of adalimumab 40 mg every other week (double-blind or open-label).

Serious adverse events	DB Adalimumab 40 mg Eow	DB Placebo Eow	OL Adalimumab 40 mg Eow
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 25 (8.00%)	7 / 25 (28.00%)	20 / 32 (62.50%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Investigations			
Blood phorphorus decreased			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Anaemia postoperative			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac disorder			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Somnolence			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 32 (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
Depressed level of consciousness			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	1 / 25 (4.00%)	4 / 25 (16.00%)	15 / 32 (46.88%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			

subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 32 (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
Intestinal perforation			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal stenosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal stenosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal stricture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal stenosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 32 (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
Liver abscess			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	0 / 32 (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
Perianal abscess			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis viral			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdiaphragmatic abscess			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
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			
Malnutrition			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Any Adalimumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	49 / 79 (62.03%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Investigations			
Blood phorphorus decreased			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Anaemia postoperative			

alternative assessment type: Systematic				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Cardiac disorder				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Somnolence				
subjects affected / exposed	0 / 79 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depressed level of consciousness				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoaesthesia				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
alternative assessment type: Systematic				

subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Iron deficiency anaemia				
alternative assessment type: Systematic				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Pyrexia				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malaise				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Systemic inflammatory response syndrome				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Crohn's disease				
subjects affected / exposed	26 / 79 (32.91%)			
occurrences causally related to treatment / all	0 / 30			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	3 / 79 (3.80%)			
occurrences causally related to treatment / all	3 / 4			
deaths causally related to treatment / all	0 / 0			
Subileus				

subjects affected / exposed	0 / 79 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal perforation				
subjects affected / exposed	2 / 79 (2.53%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Duodenal stenosis				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal stenosis				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Anal fistula				
subjects affected / exposed	2 / 79 (2.53%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Anal stenosis				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	4 / 79 (5.06%)			
occurrences causally related to treatment / all	1 / 5			
deaths causally related to treatment / all	0 / 0			
Large intestinal stricture				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				

subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	3 / 79 (3.80%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Small intestinal stenosis				
subjects affected / exposed	2 / 79 (2.53%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Ovarian cyst				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholangitis				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bile duct stone				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dyspnoea exertional			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngolaryngeal pain			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences causally related to treatment / all	2 / 4		
deaths causally related to treatment / all	0 / 0		
Liver abscess			
subjects affected / exposed	0 / 79 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Perianal abscess			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enterocolitis viral			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Cellulitis			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdiaphragmatic abscess			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	2 / 79 (2.53%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	DB Adalimumab 40 mg Eow	DB Placebo Eow	OL Adalimumab 40 mg Eow
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 25 (72.00%)	16 / 25 (64.00%)	30 / 32 (93.75%)
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	3 / 25 (12.00%)	1 / 25 (4.00%)	10 / 32 (31.25%)
occurrences (all)	6	1	17
Injection site reaction			
subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	2	0	2

Pain			
subjects affected / exposed	0 / 25 (0.00%)	2 / 25 (8.00%)	1 / 32 (3.13%)
occurrences (all)	0	2	1
Pyrexia			
subjects affected / exposed	2 / 25 (8.00%)	1 / 25 (4.00%)	5 / 32 (15.63%)
occurrences (all)	2	1	7
Oedema peripheral			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Chest pain			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	2 / 32 (6.25%)
occurrences (all)	0	1	2
Malaise			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	2 / 32 (6.25%)
occurrences (all)	0	1	3
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	4 / 25 (16.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences (all)	4	0	1
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	5 / 32 (15.63%)
occurrences (all)	0	0	6
Cough			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	1 / 32 (3.13%)
occurrences (all)	0	1	1
Rhinitis allergic			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	1	0	2
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	4

Depression			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Investigations			
Antinuclear antibody increased			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	2	0	2
Blood creatine phosphokinase increased			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 25 (4.00%)	3 / 25 (12.00%)	3 / 32 (9.38%)
occurrences (all)	1	4	3
C-reactive protein increased			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
DNA antibody positive			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	2 / 32 (6.25%)
occurrences (all)	0	1	2
Gamma-glutamyltransferase increased			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences (all)	1	0	1
Lymphocyte morphology abnormal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			

subjects affected / exposed	1 / 25 (4.00%)	2 / 25 (8.00%)	6 / 32 (18.75%)
occurrences (all)	1	2	8
Dizziness			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	2 / 32 (6.25%)
occurrences (all)	0	1	2
Blood and lymphatic system disorders			
Iron deficiency anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	6 / 32 (18.75%)
occurrences (all)	1	0	8
Eye disorders			
Ocular hyperaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	4
Conjunctivitis			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	2 / 32 (6.25%)
occurrences (all)	1	1	2
Eye discharge			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	2 / 25 (8.00%)	3 / 25 (12.00%)	4 / 32 (12.50%)
occurrences (all)	2	3	4
Dental caries			
subjects affected / exposed	3 / 25 (12.00%)	1 / 25 (4.00%)	6 / 32 (18.75%)
occurrences (all)	3	1	6
Dyspepsia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Periproctitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	3
Abdominal pain			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	2 / 32 (6.25%)
occurrences (all)	1	1	2

Abdominal pain upper			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	1 / 32 (3.13%)
occurrences (all)	0	1	1
Stomatitis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences (all)	1	0	1
Vomiting			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	1 / 32 (3.13%)
occurrences (all)	0	1	1
Constipation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Toothache			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Hepatobiliary disorders			
Hepatic function abnormal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Liver disorder			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	4
Rash			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	3 / 32 (9.38%)
occurrences (all)	1	1	3

Eczema			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	4 / 32 (12.50%)
occurrences (all)	1	0	4
Pruritus			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	3 / 32 (9.38%)
occurrences (all)	1	1	6
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Urticaria			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	4
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	2 / 32 (6.25%)
occurrences (all)	1	1	2
Back pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	14 / 25 (56.00%)	3 / 25 (12.00%)	24 / 32 (75.00%)
occurrences (all)	24	4	76
Tinea pedis			
subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	0 / 32 (0.00%)
occurrences (all)	2	0	0
Herpes simplex			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	3 / 32 (9.38%)
occurrences (all)	1	0	8
Pharyngitis			

subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	4 / 32 (12.50%)
occurrences (all)	0	0	5
Upper respiratory tract infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	4
Enteritis infectious			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	2 / 32 (6.25%)
occurrences (all)	1	1	2
Gastroenteritis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	4 / 32 (12.50%)
occurrences (all)	1	0	4
Cystitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Influenza			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	3
Sinusitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	3
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2

Non-serious adverse events	Any Adalimumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	76 / 79 (96.20%)		
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	22 / 79 (27.85%)		
occurrences (all)	36		
Injection site reaction			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	6		
Pain			

subjects affected / exposed	1 / 79 (1.27%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	17 / 79 (21.52%)		
occurrences (all)	26		
Oedema peripheral			
subjects affected / exposed	3 / 79 (3.80%)		
occurrences (all)	3		
Chest pain			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	5		
Malaise			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	4		
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	2 / 79 (2.53%)		
occurrences (all)	3		
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	8 / 79 (10.13%)		
occurrences (all)	9		
Pharyngolaryngeal pain			
subjects affected / exposed	11 / 79 (13.92%)		
occurrences (all)	12		
Cough			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	7		
Rhinitis allergic			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	5		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	10 / 79 (12.66%)		
occurrences (all)	13		
Depression			

subjects affected / exposed	3 / 79 (3.80%)		
occurrences (all)	3		
Investigations			
Antinuclear antibody increased			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 79 (8.86%)		
occurrences (all)	7		
Blood creatine phosphokinase increased			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	7		
C-reactive protein increased			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	4		
DNA antibody positive			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	5		
Gamma-glutamyltransferase increased			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	7		
Lymphocyte morphology abnormal			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	9		
Weight decreased			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	4		
Nervous system disorders			
Headache			
subjects affected / exposed	16 / 79 (20.25%)		
occurrences (all)	33		

Dizziness			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	5		
Blood and lymphatic system disorders			
Iron deficiency anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	12 / 79 (15.19%)		
occurrences (all)	14		
Eye disorders			
Ocular hyperaemia			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	5		
Conjunctivitis			
subjects affected / exposed	3 / 79 (3.80%)		
occurrences (all)	3		
Eye discharge			
subjects affected / exposed	3 / 79 (3.80%)		
occurrences (all)	3		
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	15 / 79 (18.99%)		
occurrences (all)	18		
Dental caries			
subjects affected / exposed	16 / 79 (20.25%)		
occurrences (all)	19		
Dyspepsia			
subjects affected / exposed	3 / 79 (3.80%)		
occurrences (all)	3		
Periproctitis			
subjects affected / exposed	3 / 79 (3.80%)		
occurrences (all)	3		
Abdominal pain			
subjects affected / exposed	8 / 79 (10.13%)		
occurrences (all)	8		
Abdominal pain upper			

subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	6		
Diarrhoea			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	6		
Nausea			
subjects affected / exposed	9 / 79 (11.39%)		
occurrences (all)	9		
Stomatitis			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	7		
Vomiting			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	5		
Constipation			
subjects affected / exposed	2 / 79 (2.53%)		
occurrences (all)	2		
Toothache			
subjects affected / exposed	3 / 79 (3.80%)		
occurrences (all)	3		
Hepatobiliary disorders			
Hepatic function abnormal			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	4		
Liver disorder			
subjects affected / exposed	2 / 79 (2.53%)		
occurrences (all)	2		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	7		
Rash			
subjects affected / exposed	8 / 79 (10.13%)		
occurrences (all)	8		
Eczema			

subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	7		
Pruritus			
subjects affected / exposed	8 / 79 (10.13%)		
occurrences (all)	11		
Seborrhoeic dermatitis			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	6		
Urticaria			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	4		
Dermatitis contact			
subjects affected / exposed	2 / 79 (2.53%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	6		
Back pain			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	8		
Myalgia			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	5		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	60 / 79 (75.95%)		
occurrences (all)	213		
Tinea pedis			
subjects affected / exposed	3 / 79 (3.80%)		
occurrences (all)	3		
Herpes simplex			
subjects affected / exposed	7 / 79 (8.86%)		
occurrences (all)	28		
Pharyngitis			

subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	6		
Upper respiratory tract infection			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	7		
Enteritis infectious			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	4		
Gastroenteritis			
subjects affected / exposed	7 / 79 (8.86%)		
occurrences (all)	7		
Cystitis			
subjects affected / exposed	3 / 79 (3.80%)		
occurrences (all)	3		
Influenza			
subjects affected / exposed	3 / 79 (3.80%)		
occurrences (all)	3		
Sinusitis			
subjects affected / exposed	2 / 79 (2.53%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	2 / 79 (2.53%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 March 2007	Allowed to taper and discontinue the concomitant medication, and dose escalation of the concomitant medication after the flare for the subjects with open-label adalimumab treatment after Week 12 of Study M06-837.
09 June 2008	Allowed to have self-injection after Week 52 of Study M06-837.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported