Trial record 1 of 1 for: abbott [Lead] | M06-837
Previous Study | Return to List | Next Study

A Study of Adalimumab for the Maintenance of Clinical Remission in Japanese Subjects With Crohn's Disease

This study has been completed.

Sponsor:
Abbott

Collaborator:
Eisai Co., Ltd.

Information provided by (Responsible Party):
Abbott

ClinicalTrials.gov Identifier:
NCT00445432

First received: March 7, 2007
Last updated: February 1, 2012
Last verified: February 2012
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: March 31, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Crohn's Disease
Interventions:	Biological: adalimumab Other: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

No text entered.

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week
OL Adalimumab 40 mg Eow	Open-label adalimumab 40 mg every other week
Any Adalimumab	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).

Participant Flow for 2 periods

Period 1: Through Week 52 of NCT00445432 (M06-837)

	DB Adalimumab 40 mg Eow	Placebo Eow	OL Adalimumab 40 mg Eow	Any Adalimumab
STARTED	25	25	32	0 [1]
COMPLETED	10	2	21	0
NOT COMPLETED	15	23	11	0
Adverse Event	1	2	7	0
Withdrawal by Subject	0	0	2	0
Moved to open-label	14	20	0	0
Not specified	0	1	2	0

[1] This treatment group is not applicable for this period.

Period 2: 148 Weeks of Adalimumab Treatment

	DB Adalimumab 40 mg Eow	Placebo Eow	OL Adalimumab 40 mg Eow	Any Adalimumab
STARTED	0 [1]	0 [1]	0 [1]	79 [2]
COMPLETED	0	0	0	35
NOT COMPLETED	0	0	0	44
Adverse Event	0	0	0	32
Withdrawal by Subject	0	0	0	3
Not specified	0	0	0	9

[1] This group is not applicable for this period.
[2] 3 participants discontinued while receiving double-blind placebo and never received any adalimumab

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week
OL Adalimumab 40 mg Eow	Open-label adalimumab 40 mg every other week
Total	Total of all reporting groups

Baseline Measures

	DB Adalimumab 40 mg Eow	Placebo Eow	OL Adalimumab 40 mg Eow	Total
Number of Participants [units: participants]	25	25	32	82
Age [units: participants]				
<=18 years	0	2	3	5
Between 18 and 65 years	25	23	29	77
>=65 years	0	0	0	0
Age [units: years] Mean ± Standard Deviation	31.60 ± 7.171	30.80 ± 10.939	30.75 ± 8.359	31.02 ± 8.808
Gender [units: participants]				
Female	9	10	14	33
Male	16	15	18	49
Region of Enrollment [units: participants]				
Japan	25	25	32	82

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Who Had Clinical Remission at Week 52 of Double-blind Treatment [Time Frame: Week 52 of double-blind treatment]

Measure Type	Primary
Measure Title	Number of Participants Who Had Clinical Remission at Week 52 of Double-blind Treatment
Measure Description	Clinical remission=Crohn's Disease (CD) 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.
Time Frame	Week 52 of double-blind treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

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.

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week

Measured Values

	DB Adalimumab 40 mg Eow	Placebo Eow
Number of Participants Analyzed [units: participants]	**21**	**22**
Number of Participants Who Had Clinical Remission at Week 52 of Double-blind Treatment [units: Participants]	**8**	**2**

No statistical analysis provided for Number of Participants Who Had Clinical Remission at Week 52 of Double-blind Treatment

2. 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 [Time Frame: Week 52 of double-blind treatment]

Measure Type	Secondary
Measure 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
Measure 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.
Time Frame	Week 52 of double-blind treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

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). Nonresponder imputation (NRI) (CR-70 not achieved) used for DB treatments; LOCF for OL treatment.

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week
OL Adalimumab 40 mg Eow	Open-label adalimumab 40 mg every other week

Measured Values

	DB Adalimumab 40 mg Eow	Placebo Eow	OL Adalimumab 40 mg Eow
Number of Participants Analyzed [units: participants]	**21**	**22**	**32**
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 [units: Participants]	**9**	**2**	**10**

No statistical analysis provided for 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

3. 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 [Time Frame: Week 52 of double-blind treatment]

Measure Type	Secondary
Measure 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
Measure 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.
Time Frame	Week 52 of double-blind treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

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.

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week
OL Adalimumab 40 mg Eow	Open-label adalimumab 40 mg every other week

Measured Values

	DB Adalimumab 40 mg Eow	Placebo Eow	OL Adalimumab 40 mg Eow
Number of Participants Analyzed [units: participants]	**21**	**22**	**32**
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 [units: Participants]	**8**	**2**	**8**

No statistical analysis provided for 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

4. Secondary: Change in Crohn's Disease Activity Index From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment [Time Frame: Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment]

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

Time Frame	Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

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. Last observation carried forward (LOCF) used for missing data.

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week

Measured Values

	DB Adalimumab 40 mg Eow	Placebo Eow
Number of Participants Analyzed [units: participants]	**21**	**22**
Change in Crohn's Disease Activity Index From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment [units: units on a scale] Mean ± Standard Deviation	**-83.7 ± 110.26**	**-9.1 ± 110.41**

No statistical analysis provided for Change in Crohn's Disease Activity Index From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment

5. Secondary: Number of Participants Who Had Clinical Remission at Week 52 of Open-label Treatment [Time Frame: Week 52 of open-label treatment]

Measure Type	Secondary
Measure Title	Number of Participants Who Had Clinical Remission at Week 52 of Open-label Treatment
Measure Description	Clinical remission=Crohn's Disease (CD) 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.
Time Frame	Week 52 of open-label treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

OL efficacy set (assigned to OL treatment at Week 0, received >= 1 dose of OL study drug). Last observation carried forward (LOCF) used for missing data.

Reporting Groups

	Description
OL Adalimumab 40 mg Eow	Open-label adalimumab 40 mg every other week

Measured Values

	OL Adalimumab 40 mg Eow
Number of Participants Analyzed [units: participants]	**32**
Number of Participants Who Had Clinical Remission at Week 52 of Open-label Treatment [units: Participants]	**5**

No statistical analysis provided for Number of Participants Who Had Clinical Remission at Week 52 of Open-label Treatment

6. 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 [Time Frame: Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment]

Measure Type	Secondary
Measure 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
Measure 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.
Time Frame	Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

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. Last observation carried forward (LOCF) used for missing data.

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week

Measured Values

	DB Adalimumab 40 mg Eow	Placebo Eow
Number of Participants Analyzed [units: participants]	**21**	**22**
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 [units: units on a scale] Mean ± Standard Deviation	**-0.8 ± 1.89**	**-0.2 ± 1.34**

No statistical analysis provided for 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

7. Secondary: Change in Inflammatory Bowel Disease Questionnaire (IBDQ) From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment [Time Frame: Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment]

Measure Type	Secondary
Measure Title	Change in Inflammatory Bowel Disease Questionnaire (IBDQ) From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment
Measure 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.
Time Frame	Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

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. Last observation carried forward (LOCF) used for missing data.

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week

Measured Values

	DB Adalimumab 40 mg Eow	Placebo Eow
Number of Participants Analyzed [units: participants]	**16**	**14**
Change in Inflammatory Bowel Disease Questionnaire (IBDQ) From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment	**27.8 ± 32.44**	**1.8 ± 35.42**

[units: units on a scale] Mean ± Standard Deviation		

No statistical analysis provided for Change in Inflammatory Bowel Disease Questionnaire (IBDQ) From Baseline of Lead-in Study (NCT00445939) to Week 52 of Double-blind Treatment

8. 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 [Time Frame: Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment]

Measure Type	Secondary
Measure 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
Measure 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).
Time Frame	Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
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. Last observation carried forward (LOCF) used for missing data.

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week

Measured Values

	DB Adalimumab 40 mg Eow	Placebo Eow
Number of Participants Analyzed [units: participants]	**16**	**14**
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 [units: units on a scale] Mean ± Standard Deviation	**4.4 ± 9.09**	**0.2 ± 6.31**

No statistical analysis provided for 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

9. 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 [Time Frame: Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment]

Measure Type	Secondary
Measure 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
Measure 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).
Time Frame	Baseline of lead-in study (NCT00445939) to Week 52 of double-blind treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

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. Last observation carried forward (LOCF) used for missing data.

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week

Measured Values

	DB Adalimumab 40 mg Eow	Placebo Eow
Number of Participants Analyzed [units: participants]	**16**	**14**
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 [units: units on a scale] Mean ± Standard Deviation	**9.6 ± 8.37**	**0.3 ± 14.15**

No statistical analysis provided for 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

10. Other Pre-specified: Number of Participants Who Had Clinical Remission at Week 148 [Time Frame: Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)]

Measure Type	Other Pre-specified
Measure Title	Number of Participants Who Had Clinical Remission at Week 148
Measure Description	Clinical remission = Crohn's Disease (CD) 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.

Time Frame	Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data is reported as observed cases. No imputation technique was used.

Reporting Groups

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

Measured Values

	Any Adalimumab
Number of Participants Analyzed [units: participants]	**36**
Number of Participants Who Had Clinical Remission at Week 148 [units: participants]	**21**

No statistical analysis provided for Number of Participants Who Had Clinical Remission at Week 148

11. 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 [Time Frame: Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)]

Measure Type	Other Pre-specified
Measure 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
Measure 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.
Time Frame	Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data is reported as observed cases. No imputation technique was used.

Reporting Groups

	Description

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

Measured Values

	Any Adalimumab
Number of Participants Analyzed [units: participants]	**36**
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 [units: participants]	**28**

No statistical analysis provided for 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

12. 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 [Time Frame: Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)]

Measure Type	Other Pre-specified
Measure 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
Measure 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.
Time Frame	Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data is reported as observed cases. No imputation technique was used.

Reporting Groups

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

Measured Values

	Any Adalimumab
Number of Participants Analyzed [units: participants]	**36**

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 [units: participants]	26

No statistical analysis provided for 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

13. Other Pre-specified: Change in Crohn's Disease Activity Index From Baseline of Lead-in Study (NCT00445939) to Week 148 [Time Frame: Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)]

Measure Type	Other Pre-specified
Measure Title	Change in Crohn's Disease Activity Index From Baseline of Lead-in Study (NCT00445939) to Week 148
Measure 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.
Time Frame	Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data is reported as observed cases. No imputation technique was used.

Reporting Groups

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

Measured Values

	Any Adalimumab
Number of Participants Analyzed [units: participants]	**36**
Change in Crohn's Disease Activity Index From Baseline of Lead-in Study (NCT00445939) to Week 148 [units: units on a scale] Mean ± Standard Deviation	**-143.0 ± 102.49**

No statistical analysis provided for Change in Crohn's Disease Activity Index From Baseline of Lead-in Study (NCT00445939) to Week 148

14. 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 [Time Frame: Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)]

Measure Type	Other Pre-specified
Measure Title	Change in International Organization for the Study of Inflammatory Bowel Disease (IOIBD) Score From Baseline of Lead-in Study (NCT00445939) to Week 148
Measure 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.
Time Frame	Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data is reported as observed cases. No imputation technique was used.

Reporting Groups

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

Measured Values

	Any Adalimumab
Number of Participants Analyzed [units: participants]	**35**
Change in International Organization for the Study of Inflammatory Bowel Disease (IOIBD) Score From Baseline of Lead-in Study (NCT00445939) to Week 148 [units: units on a scale] Mean ± Standard Deviation	**-1.7 ± 1.41**

No statistical analysis provided for Change in International Organization for the Study of Inflammatory Bowel Disease (IOIBD) Score From Baseline of Lead-in Study (NCT00445939) to Week 148

15. Other Pre-specified: Change in Inflammatory Bowel Disease Questionnaire (IBDQ) From Baseline of Lead-in Study (NCT00445939) to Week 148 [Time Frame: Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)]

Measure Type	Other Pre-specified

Measure Title	Change in Inflammatory Bowel Disease Questionnaire (IBDQ) From Baseline of Lead-in Study (NCT00445939) to Week 148
Measure 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.
Time Frame	Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data is reported as observed cases. No imputation technique was used.

Reporting Groups

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

Measured Values

	Any Adalimumab
Number of Participants Analyzed [units: participants]	**37**
Change in Inflammatory Bowel Disease Questionnaire (IBDQ) From Baseline of Lead-in Study (NCT00445939) to Week 148 [units: units on a scale] Mean ± Standard Deviation	**27.2 ± 31.22**

No statistical analysis provided for Change in Inflammatory Bowel Disease Questionnaire (IBDQ) From Baseline of Lead-in Study (NCT00445939) to Week 148

16. 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 [Time Frame: Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)]

Measure Type	Other Pre-specified
Measure Title	Change in Physical Component of the Short Form-36 Health Survey From Baseline of the Lead-in Study (NCT00445939) to Week 148
Measure 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.
Time Frame	Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data is reported as observed cases. No imputation technique was used.

Reporting Groups

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

Measured Values

	Any Adalimumab
Number of Participants Analyzed [units: participants]	**37**
Change in Physical Component of the Short Form-36 Health Survey From Baseline of the Lead-in Study (NCT00445939) to Week 148 [units: units on a scale] Mean ± Standard Deviation	**5.44 ± 7.245**

No statistical analysis provided for Change in Physical Component of the Short Form-36 Health Survey From Baseline of the Lead-in Study (NCT00445939) to Week 148

17. 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 [Time Frame: Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)]

Measure Type	Other Pre-specified
Measure Title	Change in Mental Component of the Short Form-36 Health Survey From Baseline of the Lead-in Study (NCT00445939) to Week 148
Measure 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).
Time Frame	Baseline of lead-in study (NCT00445939) to Week 148 relative to the first dose of adalimumab in NCT00445432 (Study M06-837)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data is reported as observed cases. No imputation technique was used.

Reporting Groups

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

Measured Values

	Any Adalimumab
Number of Participants Analyzed [units: participants]	**37**
Change in Mental Component of the Short Form-36 Health Survey From Baseline of the Lead-in Study (NCT00445939) to Week 148 [units: units on a scale] Mean ± Standard Deviation	**6.44 ± 11.173**

No statistical analysis provided for Change in Mental Component of the Short Form-36 Health Survey From Baseline of the Lead-in Study (NCT00445939) to Week 148

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	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.
Additional Description	No text entered.

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week
OL Adalimumab 40 mg Eow	Open-label adalimumab 40 mg every other week
Any Adalimumab	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	Placebo Eow	OL Adalimumab 40 mg Eow	Any Adalimumab
Total, serious adverse events				
# participants affected / at risk	**2/25 (8.00%)**	**6/25 (24.00%)**	**13/32 (40.63%)**	**49/79 (62.03%)**
Blood and lymphatic system disorders				

Anaemia † 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Iron deficiency anaemia † 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Cardiac disorders				
Cardiac disorder * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Gastrointestinal disorders				
Crohn's disease * 1				
# participants affected / at risk	1/25 (4.00%)	3/25 (12.00%)	9/32 (28.13%)	26/79 (32.91%)
Intestinal obstruction * 1				
# participants affected / at risk	1/25 (4.00%)	0/25 (0.00%)	1/32 (3.13%)	3/79 (3.80%)
Intestinal perforation * 1				
# participants affected / at risk	0/25 (0.00%)	1/25 (4.00%)	0/32 (0.00%)	2/79 (2.53%)
Subileus * 1				
# participants affected / at risk	0/25 (0.00%)	1/25 (4.00%)	0/32 (0.00%)	0/79 (0.00%)
Duodenal stenosis * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	1/32 (3.13%)	1/79 (1.27%)
Intestinal stenosis * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	1/32 (3.13%)	1/79 (1.27%)
Anal fistula * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	2/79 (2.53%)
Anal stenosis * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)

Ileus [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)
Large intestinal stricture [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Nausea [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Peritonitis [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	3/79 (3.80%)
Small intestinal stenosis [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	2/79 (2.53%)
General disorders				
Malaise [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Pyrexia [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Systemic inflammatory response syndrome [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Hepatobiliary disorders				
Bile duct stone [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Cholangitis [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Cholecystitis [*1]				
	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)

# participants affected / at risk				
Cholelithiasis [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Infections and infestations				
Abdominal abscess [*1]				
# participants affected / at risk	1/25 (4.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)
Liver abscess [*1]				
# participants affected / at risk	0/25 (0.00%)	1/25 (4.00%)	0/32 (0.00%)	0/79 (0.00%)
Perianal abscess [*1]				
# participants affected / at risk	0/25 (0.00%)	1/25 (4.00%)	0/32 (0.00%)	1/79 (1.27%)
Enterocolitis viral [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	1/32 (3.13%)	1/79 (1.27%)
Bacteraemia [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Cellulitis [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Gastroenteritis [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Pneumonia [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Subdiaphragmatic abscess [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Injury, poisoning and procedural complications				

Anaemia postoperative † 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Investigations				
Blood phorphorus decreased † 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Metabolism and nutrition disorders				
Malnutrition * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	1/32 (3.13%)	2/79 (2.53%)
Nervous system disorders				
Somnolence * 1				
# participants affected / at risk	0/25 (0.00%)	1/25 (4.00%)	0/32 (0.00%)	0/79 (0.00%)
Depressed level of consciousness * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Dizziness * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Headache * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Hypoaesthesia * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Reproductive system and breast disorders				
Ovarian cyst * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Respiratory, thoracic and mediastinal disorders				

Acute respiratory distress syndrome * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Dyspnoea exertional * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)
Pharyngolaryngeal pain * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	1/79 (1.27%)

† Events were collected by systematic assessment
* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 9.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	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.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
DB Adalimumab 40 mg Eow	Double-blind adalimumab 40 mg every other week
Placebo Eow	Double-blind adalimumab placebo every other week
OL Adalimumab 40 mg Eow	Open-label adalimumab 40 mg every other week
Any Adalimumab	All participants in this study who received at least 1 dose of adalimumab 40 mg every other week (double-blind or open-label).

Other Adverse Events

	DB Adalimumab 40 mg Eow	Placebo Eow	OL Adalimumab 40 mg Eow	Any Adalimumab
Total, other (not including serious) adverse events				

# participants affected / at risk	17/25 (68.00%)	13/25 (52.00%)	28/32 (87.50%)	73/79 (92.41%)
Blood and lymphatic system disorders				
Iron deficiency anaemia † [1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	6/32 (18.75%)	12/79 (15.19%)
Eye disorders				
Ocular hyperaemia * [1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	2/32 (6.25%)	4/79 (5.06%)
Gastrointestinal disorders				
Crohn's disease * [1]				
# participants affected / at risk	2/25 (8.00%)	4/25 (16.00%)	4/32 (12.50%)	15/79 (18.99%)
Dental caries * [1]				
# participants affected / at risk	3/25 (12.00%)	1/25 (4.00%)	3/32 (9.38%)	16/79 (20.25%)
Dyspepsia * [1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	2/32 (6.25%)	0/79 (0.00%)
Periproctitis * [1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	3/32 (9.38%)	0/79 (0.00%)
Abdominal pain * [1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	8/79 (10.13%)
Abdominal pain upper * [1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	6/79 (7.59%)
Diarrhoea * [1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	6/79 (7.59%)
Nausea * [1]				
	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	9/79 (11.39%)

# participants affected / at risk				
Stomatitis [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)
Vomiting [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	5/79 (6.33%)
General disorders				
Adverse drug reaction [*1]				
# participants affected / at risk	3/25 (12.00%)	1/25 (4.00%)	6/32 (18.75%)	22/79 (27.85%)
Injection site reaction [*1]				
# participants affected / at risk	2/25 (8.00%)	0/25 (0.00%)	2/32 (6.25%)	6/79 (7.59%)
Pain [*1]				
# participants affected / at risk	0/25 (0.00%)	2/25 (8.00%)	0/32 (0.00%)	0/79 (0.00%)
Pyrexia [*1]				
# participants affected / at risk	2/25 (8.00%)	1/25 (4.00%)	3/32 (9.38%)	17/79 (21.52%)
Oedema peripheral [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	2/32 (6.25%)	0/79 (0.00%)
Chest pain [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)
Malaise [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)
Hepatobiliary disorders				
Hepatic function abnormal [†1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)
Infections and infestations				
Nasopharyngitis [*1]				

# participants affected / at risk	14/25 (56.00%)	3/25 (12.00%)	23/32 (71.88%)	60/79 (75.95%)
Tinea pedis [*1]				
# participants affected / at risk	2/25 (8.00%)	0/25 (0.00%)	0/32 (0.00%)	0/79 (0.00%)
Herpes simplex [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	2/32 (6.25%)	7/79 (8.86%)
Pharyngitis [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	3/32 (9.38%)	5/79 (6.33%)
Upper respiratory tract infection [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	2/32 (6.25%)	6/79 (7.59%)
Enteritis infectious [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)
Gastroenteritis [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	7/79 (8.86%)
Investigations				
Antinuclear antibody increased [†1]				
# participants affected / at risk	2/25 (8.00%)	0/25 (0.00%)	0/32 (0.00%)	7/79 (8.86%)
Blood creatine phosphokinase increased [†1]				
# participants affected / at risk	1/25 (4.00%)	3/25 (12.00%)	3/32 (9.38%)	6/79 (7.59%)
C-reactive protein increased [†1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)
DNA antibody positive [†1]				
	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	5/79 (6.33%)

# participants affected / at risk				
Gamma-glutamyltransferase increased † 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	6/79 (7.59%)
Lymphocyte morphology abnormal † 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	5/79 (6.33%)
Weight decreased * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)
Metabolism and nutrition disorders				
Malnutrition * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	2/32 (6.25%)	0/79 (0.00%)
Musculoskeletal and connective tissue disorders				
Arthralgia * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	6/79 (7.59%)
Back pain * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	6/79 (7.59%)
Myalgia * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	5/79 (6.33%)
Nervous system disorders				
Headache * 1				
# participants affected / at risk	1/25 (4.00%)	2/25 (8.00%)	4/32 (12.50%)	16/79 (20.25%)
Dizziness * 1				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	5/79 (6.33%)
Psychiatric disorders				

Insomnia [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	10/79 (12.66%)
Respiratory, thoracic and mediastinal disorders				
Rhinorrhoea [*1]				
# participants affected / at risk	4/25 (16.00%)	0/25 (0.00%)	0/32 (0.00%)	8/79 (10.13%)
Pharyngolaryngeal pain [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	4/32 (12.50%)	11/79 (13.92%)
Cough [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	6/79 (7.59%)
Rhinitis allergic [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)
Skin and subcutaneous tissue disorders				
Acne [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	2/32 (6.25%)	5/79 (6.33%)
Rash [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	3/32 (9.38%)	8/79 (10.13%)
Eczema [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	6/79 (7.59%)
Pruritus [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	8/79 (10.13%)
Seborrhoeic dermatitis [*1]				
# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)
Urticaria [*1]				

# participants affected / at risk	0/25 (0.00%)	0/25 (0.00%)	0/32 (0.00%)	4/79 (5.06%)

† Events were collected by systematic assessment
* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 9.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** Abbott requests that any investigator or institution that plans on presenting/publishing results disclosure, provide written notification of their request 60 days prior to their presentation/publication. Abbott requests that no presentation/publication will be instituted until 12 months after a study is completed, or after the first presentation/publication whichever occurs first. A delay may be proposed of a presentation/publication if Abbott needs to secure patent or proprietary protection.

Results Point of Contact:

Name/Title: Global Medical Services
Organization: Abbott
phone: 800-633-9110

No publications provided by Abbott

Publications automatically indexed to this study:

Watanabe M, Hibi T, Mostafa NM, Chao J, Arora V, Camez A, Petersson J, Thakkar R. Long-term safety and efficacy of adalimumab in Japanese patients with moderate to severe Crohn's disease. J Crohns Colitis. 2014 Nov 1;8(11):1407-16. doi: 10.1016/j.crohns.2014.04.012. Epub 2014 May 27.

Watanabe M, Hibi T, Lomax KG, Paulson SK, Chao J, Alam MS, Camez A; Study Investigators. Adalimumab for the induction and maintenance of clinical remission in Japanese patients with Crohn's disease. J Crohns Colitis. 2012 Mar;6(2):160-73. doi: 10.1016/j.crohns.2011.07.013. Epub 2011 Aug 26.

Responsible Party:	Abbott
ClinicalTrials.gov Identifier:	NCT00445432 History of Changes
Other Study ID Numbers:	**M06-837**
Study First Received:	March 7, 2007
Results First Received:	March 31, 2010
Last Updated:	February 1, 2012
Health Authority:	Japan: Ministry of Health, Labor and Welfare