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Trial record **2 of 2** for: C0524T17

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An Efficacy and Safety Study of Golimumab (CNTO 148) in Participants With Moderately to Severely Active Ulcerative Colitis

This study has been completed.

Sponsor:
Janssen Research & Development, LLC

Collaborator:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Janssen Research & Development, LLC

ClinicalTrials.gov Identifier:
NCT00487539

First received: June 14, 2007
Last updated: January 14, 2014
Last verified: January 2014
History of Changes

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Results First Received: April 29, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Colitis, Ulcerative
Interventions:	Biological: Placebo Biological: Golimumab 100 mg Biological: Golimumab 200 mg Biological: Golimumab 400 mg Biological: Golimumab 50 mg

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
Participants were assigned to Placebo, Golimumab 100 mg->50 mg, Golimumab 200 mg->100 mg and Golimumab 400 mg->200 mg groups for dose selection. Efficacy results were reported for only newly enrolled participants assigned to Placebo, Golimumab 200 mg->100 mg and Golimumab 400 mg->200 mg groups after dose-selection as per planned analysis.

Reporting Groups

	Description
Placebo	Placebo subcutaneous injection (given under the skin by way of a needle) matched to golimumab administered at Week 0 and Week 2. This dosing regimen was selected for the efficacy analysis (only in newly enrolled participants following dose-selection, as per planned analysis).
Golimumab 100 mg -> 50 mg	Golimumab 100 milligram (mg) subcutaneous injection was administered at Week 0 and dose was decreased to 50 mg at Week 2.
Golimumab 200 mg -> 100 mg	Golimumab 200 mg subcutaneous injection was administered at Week 0 and the dose was decreased to 100 mg at Week 2. This dosing regimen was selected for the efficacy analysis (only in newly enrolled participants following dose-selection, as per planned analysis).

Golimumab 400 mg -> 200 mg	Golimumab 400 mg subcutaneous injection was administered at Week 0 and the dose was decreased to 200 mg at Week 2. This dosing regimen was selected for the efficacy analysis (only in newly enrolled participants following dose-selection, as per planned analysis).

Participant Flow: Overall Study

	Placebo	Golimumab 100 mg -> 50 mg	Golimumab 200 mg -> 100 mg	Golimumab 400 mg -> 200 mg
STARTED	331	72	331	331
COMPLETED	324	69	328	327
NOT COMPLETED	7	3	3	4
Adverse Event	3	2	1	1
Unsatisfactory therapeutic effect	1	0	0	1
Unspecified	3	1	2	2

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
Placebo	Placebo subcutaneous injection (given under the skin by way of a needle) matched to golimumab administered at Week 0 and Week 2.
Golimumab 100 mg -> 50 mg	Golimumab 100 milligram (mg) subcutaneous injection was administered at Week 0 and dose was decreased to 50 mg at Week 2.
Golimumab 200 mg -> 100 mg	Golimumab 200 mg subcutaneous injection was administered at Week 0 and dose was decreased to 100 mg at Week 2.
Golimumab 400 mg -> 200 mg	Golimumab 400 mg subcutaneous injection was administered at Week 0 and dose was decreased to 200 mg at Week 2.
Total	Total of all reporting groups

Baseline Measures

	Placebo	Golimumab 100 mg -> 50 mg	Golimumab 200 mg -> 100 mg	Golimumab 400 mg -> 200 mg	Total
Number of Participants [units: participants]	331	72	331	331	1065
Age [units: Years] Mean (Standard Deviation)	39 (13.04)	40.9 (12.19)	40 (13.54)	40.7 (13.75)	40 (13.37)
Gender [units: Participants]					
Female	156	32	151	130	469
Male	175	40	180	201	596

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Clinical Response at Week 6 [Time Frame: Baseline, Week 6]

Measure Type	Primary
Measure Title	Number of Participants With Clinical Response at Week 6
Measure Description	Clinical response is defined as decrease from baseline in Mayo score by greater than or equal to 30 percent and greater than or equal to 3, with either a decrease from baseline in rectal bleeding sub-score of greater than or equal to 1 or a rectal bleeding sub-score of 0 or 1. The Mayo score is sum of 4 sub-scores (i.e., stool frequency, rectal bleeding, endoscopic findings, and physician's global assessment); each rated on a scale from 0 to 3, with higher scores indicating more severe disease. The total Mayo score value ranges from 0 to 12.
Time Frame	Baseline, Week 6
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.
Efficacy analysis population included all the participants who were randomly assigned to the study after the dose selection.

Reporting Groups

	Description
Placebo	Placebo subcutaneous injection (given under the skin by way of a needle) matched to golimumab administered at Week 0 and Week 2.
Golimumab 200 mg -> 100 mg	Golimumab 200 mg subcutaneous injection was administered at Week 0 and dose was decreased to 100 mg at Week 2.
Golimumab 400 mg -> 200 mg	Golimumab 400 mg subcutaneous injection was administered at Week 0 and dose was decreased to 200 mg at Week 2.

Measured Values

	Placebo	**Golimumab 200 mg -> 100 mg**	**Golimumab 400 mg -> 200 mg**
Number of Participants Analyzed [units: participants]	**251**	**253**	**257**
Number of Participants With Clinical Response at Week 6 [units: Participants]	**76**	**129**	**141**

Statistical Analysis 1 for Number of Participants With Clinical Response at Week 6

Groups [1]	Placebo vs. Golimumab 200 mg -> 100 mg
Method [2]	Chi-squared
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Number of Participants With Clinical Response at Week 6

Groups [1]	Placebo vs. Golimumab 400 mg -> 200 mg
Method [2]	Chi-squared
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

2. Secondary: Number of Participants With Clinical Remission at Week 6 [Time Frame: Week 6]

Measure Type	Secondary
Measure Title	Number of Participants With Clinical Remission at Week 6
Measure Description	Clinical remission is defined as a Mayo score of less than or equal to 2, with no individual sub-score greater than 1. The Mayo score is sum of 4 sub-scores (i.e., stool frequency, rectal bleeding, endoscopic findings, and physician's global assessment); each rated on a scale from 0 to 3, with higher scores indicating more severe disease. The total Mayo score value ranges from 0 to 12.
Time Frame	Week 6
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.
Efficacy analysis population included all the participants who were randomly assigned to the study after the dose selection.

Reporting Groups

	Description
Placebo	Placebo subcutaneous injection (given under the skin by way of a needle) matched to golimumab administered at Week 0 and Week 2.
Golimumab 200 mg -> 100 mg	Golimumab 200 mg subcutaneous injection was administered at Week 0 and dose was decreased to 100 mg at Week 2.
Golimumab 400 mg -> 200 mg	Golimumab 400 mg subcutaneous injection was administered at Week 0 and dose was decreased to 200 mg at Week 2.

Measured Values

	Placebo	**Golimumab 200 mg -> 100 mg**	**Golimumab 400 mg -> 200 mg**
Number of Participants Analyzed [units: participants]	**251**	**253**	**257**
Number of Participants With Clinical Remission at Week 6 [units: Participants]	**16**	**45**	**46**

Statistical Analysis 1 for Number of Participants With Clinical Remission at Week 6

Groups [1]	Placebo vs. Golimumab 200 mg -> 100 mg
Method [2]	Chi-squared
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Number of Participants With Clinical Remission at Week 6

Groups [1]	Placebo vs. Golimumab 400 mg -> 200 mg
Method [2]	Chi-squared
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

3. Secondary: Number of Participants With Mucosal Healing at Week 6 [Time Frame: Week 6]

Measure Type	Secondary
Measure Title	Number of Participants With Mucosal Healing at Week 6
Measure Description	Mucosal healing is determined from the endoscopy sub-score of the Mayo score. Mucosal healing is defined as an endoscopy sub-score of 0 or 1. Higher score indicates higher severity of disease. Endoscopy sub-score ranges from 0 (normal or inactive disease) to 3 (severe disease; spontaneous bleeding and ulceration).
Time Frame	Week 6
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.
Efficacy analysis population included all the participants who were randomly assigned to the study after the dose selection.

Reporting Groups

	Description
Placebo	Placebo subcutaneous injection (given under the skin by way of a needle) matched to golimumab administered at Week 0 and Week 2.
Golimumab 200 mg -> 100 mg	Golimumab 200 mg subcutaneous injection was administered at Week 0 and dose was decreased to 100 mg at Week 2.
Golimumab 400 mg -> 200 mg	Golimumab 400 mg subcutaneous injection was administered at Week 0 and dose was decreased to 200 mg at Week 2.

Measured Values

	Placebo	Golimumab 200 mg -> 100 mg	Golimumab 400 mg -> 200 mg
Number of Participants Analyzed [units: participants]	**251**	**253**	**257**
Number of Participants With Mucosal Healing at Week 6 [units: Participants]	**72**	**107**	**116**

Statistical Analysis 1 for Number of Participants With Mucosal Healing at Week 6

Groups [1]	Placebo vs. Golimumab 200 mg -> 100 mg
Method [2]	Chi-squared
P Value [3]	0.0014

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Number of Participants With Mucosal Healing at Week 6

Groups [1]	Placebo vs. Golimumab 400 mg -> 200 mg
Method [2]	Chi-squared
P Value [3]	0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

4. Secondary: Change From Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Week 6 [Time Frame: Baseline to Week 6]

Measure Type	Secondary
Measure Title	Change From Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Week 6
Measure Description	The IBDQ is used to measure disease specific quality of life on a 32 Likert-scaled items questionnaire. The IBDQ scale contains 4 component subscales: bowel symptoms, systemic symptoms, emotional function and social function with scores ranging from 10 to 70, 5 to 35, 12 to 84 and 5 to 35 respectively and the total score ranges from 32 to 224. Higher scores indicate better health related quality of life.
Time Frame	Baseline to Week 6
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.
Efficacy analysis population included all the participants who were randomly assigned to the study after the dose selection. 'N' (number of participants analyzed) signifies those participants who were evaluable for this measure.

Reporting Groups

	Description
Placebo	Placebo subcutaneous injection (given under the skin by way of a needle) matched to golimumab administered at Week 0 and Week 2.
Golimumab 200 mg -> 100 mg	Golimumab 200 mg subcutaneous injection was administered at Week 0 and dose was decreased to 100 mg at Week 2.
Golimumab 400 mg -> 200 mg	Golimumab 400 mg subcutaneous injection was administered at Week 0 and dose was decreased to 200 mg

	at Week 2.

Measured Values

	Placebo	Golimumab 200 mg -> 100 mg	Golimumab 400 mg -> 200 mg
Number of Participants Analyzed [units: participants]	**250**	**252**	**255**
Change From Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Week 6 [units: Units on a Scale] Mean (Standard Deviation)			
Baseline	**129.6 (32.61)**	**131.7 (33.93)**	**127.2 (33.90)**
Change at Week 6	**14.8 (31.25)**	**27.0 (33.72)**	**26.9 (34.28)**

Statistical Analysis 1 for Change From Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Week 6

Groups [1]	Placebo vs. Golimumab 200 mg -> 100 mg
Method [2]	ANOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	on the van der Waerden normal scores
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Change From Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Week 6

Groups [1]	Placebo vs. Golimumab 400 mg -> 200 mg
Method [2]	ANOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	on the van der Waerden normal scores
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	6 weeks for participants who entered the maintenance study. 16 weeks following the last study agent administration for participants who did not enter the maintenance study.
Additional Description	The safety population reflects the "as treated" population: 1 participant out of the 331 randomized to placebo, received golimumab 100 mg at Week 0 and is included in the 200 mg -> 100 mg group; 1 participant out of the 331 randomized to the 200 mg -> 100 mg group, received 200 mg golimumab at Week 2 and is included in the 400 mg -

	> 200 mg group.

Reporting Groups

	Description
Placebo	Placebo subcutaneous injection (given under the skin by way of a needle) matched to golimumab administered at Week 0 and Week 2.
Golimumab 100 mg -> 50 mg	Golimumab 100 milligram (mg) subcutaneous injection was administered at Week 0 and dose was decreased to 50 mg at Week 2.
Golimumab 200 mg -> 100 mg	Golimumab 200 mg subcutaneous injection was administered at Week 0 and dose was decreased to 100 mg at Week 2.
Golimumab 400 mg -> 200 mg	Golimumab 400 mg subcutaneous injection was administered at Week 0 and dose was decreased to 200 mg at Week 2.

Serious Adverse Events

	Placebo	Golimumab 100 mg -> 50 mg	Golimumab 200 mg -> 100 mg	Golimumab 400 mg -> 200 mg
Total, serious adverse events				
# participants affected / at risk	**20/330 (6.06%)**	**3/71 (4.23%)**	**10/331 (3.02%)**	**15/332 (4.52%)**
Blood and lymphatic system disorders				
Anaemia [*1]				
# participants affected / at risk	**2/330 (0.61%)**	**0/71 (0.00%)**	**3/331 (0.91%)**	**0/332 (0.00%)**
Gastrointestinal disorders				
Abdominal Pain [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**1/332 (0.30%)**
Abdominal Pain Upper [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**1/331 (0.30%)**	**0/332 (0.00%)**
Colitis Ulcerative [*1]				
# participants affected / at risk	**8/330 (2.42%)**	**1/71 (1.41%)**	**3/331 (0.91%)**	**7/332 (2.11%)**
Nausea [*1]				
# participants affected / at risk	**1/330 (0.30%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**0/332 (0.00%)**
Vomiting [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**1/332 (0.30%)**
General disorders				
Adverse Drug Reaction [*1]				
# participants affected / at risk	**1/330 (0.30%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**0/332 (0.00%)**
Pyrexia [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**1/331 (0.30%)**	**1/332 (0.30%)**
Infections and infestations				
Anal Abscess [*1]				
# participants affected / at risk	**1/330 (0.30%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**1/332 (0.30%)**
Brain Abscess [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**1/332 (0.30%)**

Bronchitis [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**1/332 (0.30%)**
Candidiasis [*1]				
# participants affected / at risk	**1/330 (0.30%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**0/332 (0.00%)**
Cellulitis [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**1/332 (0.30%)**
Cytomegalovirus Infection [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**1/71 (1.41%)**	**0/331 (0.00%)**	**0/332 (0.00%)**
Enterocolitis Infectious [*1]				
# participants affected / at risk	**1/330 (0.30%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**0/332 (0.00%)**
Gastroenteritis [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**1/331 (0.30%)**	**0/332 (0.00%)**
Gastroenteritis Viral [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**1/332 (0.30%)**
Haematoma Infection [*1]				
# participants affected / at risk	**1/330 (0.30%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**0/332 (0.00%)**
Herpes Simplex [*1]				
# participants affected / at risk	**1/330 (0.30%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**0/332 (0.00%)**
Pneumonia [*1]				
# participants affected / at risk	**1/330 (0.30%)**	**0/71 (0.00%)**	**1/331 (0.30%)**	**0/332 (0.00%)**
Rectal Abscess [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**1/332 (0.30%)**
Viral Infection [*1]				
# participants affected / at risk	**1/330 (0.30%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**0/332 (0.00%)**
Injury, poisoning and procedural complications				
Ankle Fracture [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**1/71 (1.41%)**	**0/331 (0.00%)**	**0/332 (0.00%)**
Fall [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**1/71 (1.41%)**	**0/331 (0.00%)**	**0/332 (0.00%)**
Investigations				
Haemoglobin Decreased [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**1/331 (0.30%)**	**0/332 (0.00%)**
Volume Blood Decreased [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**1/332 (0.30%)**
Metabolism and nutrition disorders				
Dehydration [*1]				
# participants affected / at risk	**2/330 (0.61%)**	**0/71 (0.00%)**	**0/331 (0.00%)**	**0/332 (0.00%)**
Malnutrition [*1]				

# participants affected / at risk	1/330 (0.30%)	0/71 (0.00%)	0/331 (0.00%)	0/332 (0.00%)
Musculoskeletal and connective tissue disorders				
Arthropathy * 1				
# participants affected / at risk	1/330 (0.30%)	0/71 (0.00%)	0/331 (0.00%)	0/332 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Carcinoma in Situ * 1				
# participants affected / at risk	0/330 (0.00%)	0/71 (0.00%)	0/331 (0.00%)	1/332 (0.30%)
Colon Cancer * 1				
# participants affected / at risk	0/330 (0.00%)	0/71 (0.00%)	0/331 (0.00%)	1/332 (0.30%)
Thyroid Cancer * 1				
# participants affected / at risk	1/330 (0.30%)	0/71 (0.00%)	0/331 (0.00%)	0/332 (0.00%)
Nervous system disorders				
Demyelination * 1				
# participants affected / at risk	0/330 (0.00%)	0/71 (0.00%)	0/331 (0.00%)	1/332 (0.30%)
Dizziness * 1				
# participants affected / at risk	0/330 (0.00%)	0/71 (0.00%)	0/331 (0.00%)	1/332 (0.30%)
Headache * 1				
# participants affected / at risk	0/330 (0.00%)	0/71 (0.00%)	0/331 (0.00%)	1/332 (0.30%)
Ischaemic Stroke * 1				
# participants affected / at risk	0/330 (0.00%)	0/71 (0.00%)	0/331 (0.00%)	1/332 (0.30%)
Respiratory, thoracic and mediastinal disorders				
Chronic Obstructive Pulmonary Disease * 1				
# participants affected / at risk	0/330 (0.00%)	0/71 (0.00%)	0/331 (0.00%)	1/332 (0.30%)
Lung Infiltration * 1				
# participants affected / at risk	0/330 (0.00%)	0/71 (0.00%)	0/331 (0.00%)	1/332 (0.30%)
Skin and subcutaneous tissue disorders				
Erythema Nodosum * 1				
# participants affected / at risk	3/330 (0.91%)	0/71 (0.00%)	0/331 (0.00%)	0/332 (0.00%)
Rash Macular * 1				
# participants affected / at risk	1/330 (0.30%)	0/71 (0.00%)	0/331 (0.00%)	0/332 (0.00%)
Vascular disorders				
Deep Vein Thrombosis * 1				
# participants affected / at risk	1/330 (0.30%)	0/71 (0.00%)	0/331 (0.00%)	0/332 (0.00%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 13.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	6 weeks for participants who entered the maintenance study. 16 weeks following the last study agent administration for participants who did not enter the maintenance study.
Additional Description	The safety population reflects the "as treated" population: 1 participant out of the 331 randomized to placebo, received golimumab 100 mg at Week 0 and is included in the 200 mg -> 100 mg group; 1 participant out of the 331 randomized to the 200 mg -> 100 mg group, received 200 mg golimumab at Week 2 and is included in the 400 mg -> 200 mg group.

Frequency Threshold

Threshold above which other adverse events are reported	2%

Reporting Groups

	Description
Placebo	Placebo subcutaneous injection (given under the skin by way of a needle) matched to golimumab administered at Week 0 and Week 2.
Golimumab 100 mg -> 50 mg	Golimumab 100 milligram (mg) subcutaneous injection was administered at Week 0 and dose was decreased to 50 mg at Week 2.
Golimumab 200 mg -> 100 mg	Golimumab 200 mg subcutaneous injection was administered at Week 0 and dose was decreased to 100 mg at Week 2.
Golimumab 400 mg -> 200 mg	Golimumab 400 mg subcutaneous injection was administered at Week 0 and dose was decreased to 200 mg at Week 2.

Other Adverse Events

	Placebo	**Golimumab 100 mg -> 50 mg**	**Golimumab 200 mg -> 100 mg**	**Golimumab 400 mg -> 200 mg**
Total, other (not including serious) adverse events				
# participants affected / at risk	**61/330 (18.48%)**	**18/71 (25.35%)**	**54/331 (16.31%)**	**55/332 (16.57%)**
Blood and lymphatic system disorders				
Anaemia [*1]				
# participants affected / at risk	**6/330 (1.82%)**	**2/71 (2.82%)**	**8/331 (2.42%)**	**5/332 (1.51%)**
Gastrointestinal disorders				
Abdominal Pain [*1]				
# participants affected / at risk	**5/330 (1.52%)**	**1/71 (1.41%)**	**2/331 (0.60%)**	**7/332 (2.11%)**
Colitis Ulcerative [*1]				
# participants affected / at risk	**7/330 (2.12%)**	**1/71 (1.41%)**	**4/331 (1.21%)**	**2/332 (0.60%)**
Nausea [*1]				
# participants affected / at risk	**6/330 (1.82%)**	**1/71 (1.41%)**	**3/331 (0.91%)**	**12/332 (3.61%)**
General disorders				
Injection Site Erythema [*1]				
# participants affected / at risk	**0/330 (0.00%)**	**3/71 (4.23%)**	**5/331 (1.51%)**	**4/332 (1.20%)**
Pyrexia [*1]				
# participants affected / at risk	**7/330 (2.12%)**	**2/71 (2.82%)**	**5/331 (1.51%)**	**10/332 (3.01%)**
Infections and infestations				
Nasopharyngitis [*1]				
# participants affected / at risk	**12/330 (3.64%)**	**2/71 (2.82%)**	**13/331 (3.93%)**	**8/332 (2.41%)**
Oral Herpes [*1]				
# participants affected / at risk	**1/330 (0.30%)**	**2/71 (2.82%)**	**2/331 (0.60%)**	**0/332 (0.00%)**
Musculoskeletal and connective tissue disorders				

Arthralgia * 1				
# participants affected / at risk	**7/330 (2.12%)**	**0/71 (0.00%)**	**3/331 (0.91%)**	**6/332 (1.81%)**
Back Pain * 1				
# participants affected / at risk	**2/330 (0.61%)**	**2/71 (2.82%)**	**1/331 (0.30%)**	**1/332 (0.30%)**
Nervous system disorders				
Headache * 1				
# participants affected / at risk	**17/330 (5.15%)**	**5/71 (7.04%)**	**11/331 (3.32%)**	**15/332 (4.52%)**
Psychiatric disorders				
Insomnia * 1				
# participants affected / at risk	**3/330 (0.91%)**	**2/71 (2.82%)**	**1/331 (0.30%)**	**1/332 (0.30%)**
Respiratory, thoracic and mediastinal disorders				
Cough * 1				
# participants affected / at risk	**9/330 (2.73%)**	**0/71 (0.00%)**	**3/331 (0.91%)**	**3/332 (0.90%)**
Skin and subcutaneous tissue disorders				
Rash * 1				
# participants affected / at risk	**5/330 (1.52%)**	**2/71 (2.82%)**	**2/331 (0.60%)**	**3/332 (0.90%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 13.0

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:** 12 months after study ends, Sponsor will be provided with a copy of the materials at least 45 days prior to submission, with details of proposed date, journal or conference name of publication & it will have 30 days post receipt to send a written request that the publication be delayed on the basis it exposes intellectual property that requires propriety protection but it will be only for 60 days after which Investigator will be free to publish. The participation of Sponsor will be acknowledged.

Results Point of Contact:

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Sandborn WJ, Feagan BG, Marano C, Zhang H, Strauss R, Johanns J, Adedokun OJ, Guzzo C, Colombel JF, Reinisch W, Gibson PR, Collins J, Järnerot G, Hibi T, Rutgeerts P; PURSUIT-SC Study Group. Subcutaneous golimumab induces clinical response and remission in patients with moderate-to-severe ulcerative colitis. Gastroenterology. 2014 Jan;146(1):85-95; quiz e14-5. doi: 10.1053/j.gastro.2013.05.048. Epub 2013 Jun 2.

Responsible Party:	Janssen Research & Development, LLC
ClinicalTrials.gov Identifier:	NCT00487539 History of Changes
Other Study ID Numbers:	CR014176 **C0524T17** 2006-003398-28 (EudraCT Number)
Study First Received:	June 14, 2007
Results First Received:	April 29, 2013
Last Updated:	January 14, 2014
Health Authority:	United States: Food and Drug Administration

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