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Trial record **1 of 1** for: C0524T11

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A Study of the Safety and Efficacy of Golimumab (CNTO 148) in Subjects With Active Rheumatoid Arthritis Previously Treated With Biologic Anti-TNFa Agent(s)

This study has been completed.

Sponsor:
Centocor, Inc.

Collaborator:
Schering-Plough

Information provided by (Responsible Party):
Centocor, Inc.

ClinicalTrials.gov Identifier:
NCT00299546

First received: March 3, 2006
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History of Changes

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Results First Received: May 21, 2009

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:	Arthritis, Rheumatoid
Interventions:	Drug: Placebo Biological: Golimumab 50 mg Biological: Golimumab 100 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
A total of 461 participants were enrolled at 86 sites in North America, Europe, Australia and New Zealand.

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
Group 1: Placebo	Placebo Subcutaneous (SC) injections every 4 weeks (wks) thru Wk 20 (unless early escape at Wk 16); Golimumab - if early escape, 50 mg SC injections from Wk 16 up to 5 yrs; Golimumab - 50 mg SC injections beginning Wk 24 up to 5 yrs (unless early escape); Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg and from 100 to 50mg. Duration of the blinded period was until the week-24 database lock.
Group 2: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 up to 5 yrs (unless early escape at Wk 16); Golimumab - if early escape, 100 mg SC injections every 4 wks beginning Wk 16 up to 5 yrs; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg and from 100 to 50mg. Duration of the blinded period was until the week-24 database lock.

Group 3: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50 mg. Duration of the blinded period was until the week-24 database lock.

Participant Flow: Overall Study

	Group 1: Placebo	Group 2: Golimumab 50 mg	Group 3: Golimumab 100 mg
STARTED	**155**	**153**	**153**
COMPLETED	**55**	**61**	**67**
NOT COMPLETED	**100**	**92**	**86**
Death	**3**	**2**	**0**
Lost to Follow-up	**2**	**2**	**5**
Adverse Event	**37**	**22**	**27**
Unsatisfactory therapeutic effect	**34**	**39**	**34**
Not specified	**24**	**26**	**19**
Not treated	**0**	**1**	**1**

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
Group 1: Placebo	Placebo Subcutaneous (SC) injections every 4 weeks (wks) thru Wk 20 (unless early escape at Wk 16); Golimumab - if early escape, 50 mg SC injections from Wk 16 up to 5 yrs; Golimumab - 50 mg SC injections beginning Wk 24 up to 5 yrs (unless early escape); Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg and from 100 to 50mg. Duration of the blinded period was until the week-24 database lock.
Group 2: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 up to 5 yrs (unless early escape at Wk 16); Golimumab - if early escape, 100 mg SC injections every 4 wks beginning Wk 16 up to 5 yrs; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg and from 100 to 50mg. Duration of the blinded period was until the week-24 database lock.
Group 3: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50 mg. Duration of the blinded period was until the week-24 database lock.
Total	Total of all reporting groups

Baseline Measures

	Group 1: Placebo	Group 2: Golimumab 50 mg	Group 3: Golimumab 100 mg	Total
Number of Participants [units: participants]	**155**	**153**	**153**	**461**
Age [units: years] Mean (Standard Deviation)	**54.8 (13.07)**	**53.9 (11.47)**	**53.7 (12.26)**	**54.1 (12.27)**
Gender [units: participants]				
Female	**132**	**113**	**122**	**367**
Male	**23**	**40**	**31**	**94**

Outcome Measures

Hide All Outcome Measures

1. Primary: American College of Rheumatology (ACR) 20 Response at Week 14. [Time Frame: Week 14]

Measure Type	Primary
Measure Title	American College of Rheumatology (ACR) 20 Response at Week 14.
Measure Description	ACR 20 response is an improvement of >= 20% from baseline in both the tender and swollen joint count and in at least 3 of the 5 assessments (patient's assessment of pain visual analog scale (VAS), patient's global assessment of disease activity VAS scale, Physician's global assessment of disease activity VAS scale, Health Assessment Questionnaire and C-reactive protein)
Time Frame	Week 14
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.
Randomized participants (excluding 1 site). Participants considered non-responders if used any prohibited medications or discontinued subcutaneous study agent due to lack of efficacy. Missing ACR components imputed by Last Observation Carried Forward unless all ACR components were missing; in which case considered non-responders.

Reporting Groups

	Description
Group 1: Placebo	Placebo Subcutaneous (SC) injections every 4 weeks (wks) thru Wk 20 (unless early escape at Wk 16);

	golimumab - if early escape, 50 mg SC injections from Wk 16 up to 5 yrs; golimumab - 50 mg SC injections beginning Wk 24 up to 5 yrs (unless early escape); golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg. Duration of the blinded period was until the week-24 database lock.
Group 2: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 up to 5 yrs (unless early escape at Wk 16); golimumab - if early escape, 100 mg SC injections every 4 wks beginning Wk 16 up to 5 yrs; golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg. Duration of the blinded period was until the week-24 database lock.
Group 3: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50 mg. Duration of the blinded period was until the week-24 database lock.
Combined Golimumab	Combines Group 2 (golimumab 50 mg) and Group 3 (golimumab 100 mg).

Measured Values

	Group 1: Placebo	Group 2: Golimumab 50 mg	Group 3: Golimumab 100 mg	Combined Golimumab
Number of Participants Analyzed [units: participants]	**150**	**147**	**148**	**295**
American College of Rheumatology (ACR) 20 Response at Week 14. [units: participants]	**27**	**51**	**54**	**105**

Statistical Analysis 1 for American College of Rheumatology (ACR) 20 Response at Week 14.

Groups [1]	Group 1: Placebo vs. Combined Golimumab
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null hypothesis: No difference in ACR 20 response at Wk 14 comparing Group 1 vs. Combined Groups 2 and 3. A sample size of 140 patients per group provides a >90% power assuming 50% of patients used Methotrexate (MTX) at baseline and 30% ACR 20 response in placebo and 40~55% ACR 20 response in golimumab groups.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline Methotrexate (MTX)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	A positive test is concluded if there is a significant difference between combined golimumab and placebo groups and at least one of the pair-wise comparisons at 0.05 level.

Statistical Analysis 2 for American College of Rheumatology (ACR) 20 Response at Week 14.

Groups [1]	Group 1: Placebo vs. Group 2: Golimumab 50 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null Hypothesis: No difference in ACR 20 response at Wk 14 between Group 1: Placebo and Group 2: 50 mg.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline MTX
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Test was performed because Group 1: Placebo was significantly different from Combined Groups 2 & 3.

Statistical Analysis 3 for American College of Rheumatology (ACR) 20 Response at Week 14.

Groups [1]	Group 1: Placebo vs. Group 3: Golimumab 100 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null Hypothesis: No difference in ACR 20 response at Wk 14 between Group 1: Placebo and Group 3 :100 mg.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline MTX.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Test was performed because Group 1: Placebo was significantly different from Combined Groups 2 & 3.

2. Secondary: American College of Rheumatology (ACR) 50 Response at Week 14 [Time Frame: Week 14]

Measure Type	Secondary
Measure Title	American College of Rheumatology (ACR) 50 Response at Week 14
Measure Description	Number of patients who achieved an ACR 50 response at Week (Wk) 14. ACR 50 response is an improvement of >= 50% from baseline in both the tender and swollen joint count and in at least 3 of the 5 assessments (patient's assessment of pain visual analog scale (VAS), patient's global assessemnt of disease activity VAS scale, Physician's global assessment of disease activity VAS scale, Health Assessment Questionnaire and C-reactive protein).
Time Frame	Week 14
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.
Randomized participants (excluding 1 site). Participants considered non-responders if used any prohibited medications or discontinued subcutaneous study agent due to lack of efficacy. Missing ACR components imputed by Last Observation Carried Forward unless all ACR components were missing; in which case considered non-responders.

Reporting Groups

	Description
Group 1: Placebo	Placebo Subcutaneous (SC) injections every 4 weeks (wks) thru Wk 20 (unless early escape at Wk 16); golimumab - if early escape, 50 mg SC injections from Wk 16 up to 5 yrs; golimumab - 50 mg SC injections beginning Wk 24 up to 5 yrs (unless early escape); golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg. Duration of the blinded period was until the week-24 database lock.
Group 2: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 up to 5 yrs (unless early escape at Wk 16); golimumab - if early escape, 100 mg SC injections every 4 wks beginning Wk 16 up to 5 yrs; golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg. Duration of the blinded period was until the week-24 database lock.
Group 3: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50 mg. Duration of the blinded period was until the week-24 database lock.
Combined Golimumab	Combines Group 2 (golimumab 50 mg) and Group 3 (golimumab 100 mg).

Measured Values

	Group 1: Placebo	**Group 2: Golimumab 50 mg**	**Group 3: Golimumab 100 mg**	**Combined Golimumab**
Number of Participants Analyzed [units: participants]	**150**	**147**	**148**	**295**

American College of Rheumatology (ACR) 50 Response at Week 14 [units: participants]	**10**	**22**	**27**	**49**

Statistical Analysis 1 for American College of Rheumatology (ACR) 50 Response at Week 14

Groups [1]	Group 1: Placebo vs. Combined Golimumab
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.003

[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:
	Stratified by baseline Methotrexate (MTX).
[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 American College of Rheumatology (ACR) 50 Response at Week 14

Groups [1]	Group 1: Placebo vs. Group 2: Golimumab 50 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.021

[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:
	Stratified by baseline MTX.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Test was performed because Group 1: Placebo was significantly different from Combined Groups 2 & 3.

Statistical Analysis 3 for American College of Rheumatology (ACR) 50 Response at Week 14

Groups [1]	Group 1: Placebo vs. Group 3: Golimumab 100 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.002

[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:
	Stratified by baseline MTX.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Test was performed because Group 1: Placebo was significantly different from Combined Groups 2 & 3.

3. Secondary: Disease Activity Index Score 28 (DAS 28) (Using C-reactive Protein) Response at Week 14 [Time Frame: Week 14]

Measure Type	Secondary
Measure Title	Disease Activity Index Score 28 (DAS 28) (Using C-reactive Protein) Response at Week 14
Measure Description	DAS 28 using C-reactive protein (CRP) is an index to measure disease activity in participants with rheumatoid arthritis which combines tender joint count (28 joints), swollen joint count (28 joints), CRP value, and participant's global assessment of disease activity (using a Visual Analog Scale of 0 to 100 mm). The DAS 28 score ranges from 0 (best) to 10 (worst).
Time Frame	Week 14
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.
Randomized participants (excluding 1 site). Participants considered non-responders if used any prohibited medications or discontinued subcutaneous study agent due to lack of efficacy. Missing DAS 28 components imputed by Last Observation Carried Forward unless all components were missing; in which case considered non-responders.

Reporting Groups

	Description
Group 1: Placebo	Placebo Subcutaneous (SC) injections every 4 weeks (wks) thru Wk 20 (unless early escape at Wk 16); golimumab - if early escape, 50 mg SC injections from Wk 16 up to 5 yrs; golimumab - 50 mg SC injections beginning Wk 24 up to 5 yrs (unless early escape); golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg. Duration of the blinded period was until the week-24 database lock.
Group 2: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 up to 5 yrs (unless early escape at Wk 16); golimumab - if early escape, 100 mg SC injections every 4 wks beginning Wk 16 up to 5 yrs; golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg. Duration of the blinded period was until the week-24 database lock.
Group 3: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50 mg. Duration of the blinded period was until the week-24 database

	lock.
Combined Golimumab	Combines Group 2 (golimumab 50 mg) and Group 3 (golimumab 100 mg).

Measured Values

	Group 1: Placebo	Group 2: Golimumab 50 mg	Group 3: Golimumab 100 mg	Combined Golimumab
Number of Participants Analyzed [units: participants]	**150**	**147**	**148**	**295**
Disease Activity Index Score 28 (DAS 28) (Using C-reactive Protein) Response at Week 14 [units: participants]	**44**	**82**	**87**	**169**

Statistical Analysis 1 for Disease Activity Index Score 28 (DAS 28) (Using C-reactive Protein) Response at Week 14

Groups [1]	Group 1: Placebo vs. Combined Golimumab
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001

[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:
	Stratified by baseline Methorexate (MTX).
[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 Disease Activity Index Score 28 (DAS 28) (Using C-reactive Protein) Response at Week 14

Groups [1]	Group 1: Placebo vs. Group 2: Golimumab 50 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001

[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:
	Stratified by baseline MTX.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Test was performed because Group 1: Placebo was significantly different from Combined Groups 2 & 3.

Statistical Analysis 3 for Disease Activity Index Score 28 (DAS 28) (Using C-reactive Protein) Response at Week 14

Groups [1]	Group 1: Placebo vs. Group 3: Golimumab 100 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001

[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:
	Stratified by baseline MTX.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Test was performed because Group 1: Placebo was significantly different from Combined Groups 2 & 3.

4. Secondary: American College of Rheumatology (ACR) 20 at Week 24 [Time Frame: From Baseline to Week 24]

Measure Type	Secondary
Measure Title	American College of Rheumatology (ACR) 20 at Week 24
Measure Description	Number of patients who achieved ACR 20 response at Week (Wk) 24. ACR 20 response is an improvement of >= 20% from baseline in both the tender and swollen joint count and in at least 3 of the 5 assessments (patient's assessment of pain visual analog scale (VAS), patient's global assessemnt of disease activity VAS scale, Physician's global assessment of disease activity VAS scale,HAQ and CRP)
Time Frame	From Baseline to Week 24
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.
Randomized participants (excluding 1 site). Participants considered non-responders if used any prohibited medications or discontinued SC study agent due to lack of efficacy. Missing ACR components imputed by LOCF unless all components were missing; in which case considered non-responders. Wk 16 ACR response used for change in study tx.

Reporting Groups

	Description
Group 1: Placebo	Placebo Subcutaneous (SC) injections every 4 weeks (wks) thru Wk 20 (unless early escape at Wk 16);

	golimumab - if early escape, 50 mg SC injections from Wk 16 up to 5 yrs; golimumab - 50 mg SC injections beginning Wk 24 up to 5 yrs (unless early escape); golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg. Duration of the blinded period was until the week-24 database lock.
Group 2: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 up to 5 yrs (unless early escape at Wk 16); golimumab - if early escape, 100 mg SC injections every 4 wks beginning Wk 16 up to 5 yrs; golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg. Duration of the blinded period was until the week-24 database lock.
Group 3: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50 mg. Duration of the blinded period was until the week-24 database lock.
Combined Golimumab	Combines Group 2 (golimumab 50 mg) and Group 3 (golimumab 100 mg).

Measured Values

	Group 1: Placebo	Group 2: Golimumab 50 mg	Group 3: Golimumab 100 mg	Combined Golimumab
Number of Participants Analyzed [units: participants]	**150**	**147**	**148**	**295**
American College of Rheumatology (ACR) 20 at Week 24 [units: participants]	**24**	**46**	**63**	**109**

Statistical Analysis 1 for American College of Rheumatology (ACR) 20 at Week 24

Groups [1]	Group 1: Placebo vs. Combined Golimumab
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001

[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:
	Stratified by baseline Methotrexate (MTX).
[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 American College of Rheumatology (ACR) 20 at Week 24

Groups [1]	Group 1: Placebo vs. Group 2: Golimumab 50 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.002

[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:
	Stratified by baseline MTX.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Test was performed because Group 1: Placebo was significantly different from Combined Groups 2 & 3.

Statistical Analysis 3 for American College of Rheumatology (ACR) 20 at Week 24

Groups [1]	Group 1: Placebo vs. Group 3: Golimumab 100 mg

Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001

[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:
	Stratified by baseline MTX.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Test was performed because Group 1: Placebo was significantly different from Combined Groups 2 & 3.

5. Secondary: Health Assessment Questionnaire (HAQ) Score at Week 24 [Time Frame: From Baseline to Week 24]

Measure Type	Secondary
Measure Title	Health Assessment Questionnaire (HAQ) Score at Week 24
Measure Description	Improvement from baseline in HAQ score at Week 24. This 20-question instrument assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and activities of daily living). Responses in each functional area are scored from 0, indicating no difficulty, to 3, indicating inability to perform a task in that area based on the worst score from the questions that pertain to that task. The HAQ score is determined by the average of the 8 scores; HAQ ranges from 0 to 3.
Time Frame	From Baseline to Week 24
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.
Randomized participants (excluding 1 site). Missing scores imputed by Last Observation Carried Forward. Week 16 scores were used for participants with change in study treatment.

Reporting Groups

	Description
Group 1: Placebo	Placebo Subcutaneous (SC) injections every 4 weeks (wks) thru Wk 20 (unless early escape at Wk 16); golimumab - if early escape, 50 mg SC injections from Wk 16 up to 5 yrs; golimumab - 50 mg SC injections beginning Wk 24 up to 5 yrs (unless early escape); golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg. Duration of the blinded period was until the week-24 database lock.
Group 2: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 up to 5 yrs (unless early escape at Wk 16); golimumab - if early escape, 100 mg SC injections every 4 wks beginning Wk 16 up to 5 yrs; golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100 mg. Duration of the blinded period was until the week-24 database lock.
Group 3: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50 mg. Duration of the blinded period was until the week-24 database lock.
Combined Golimumab	Combines Group 2 (golimumab 50 mg) and Group 3 (golimumab 100 mg).

Measured Values

	Group 1: Placebo	**Group 2: Golimumab 50 mg**	**Group 3: Golimumab 100 mg**	**Combined Golimumab**
Number of Participants Analyzed [units: participants]	**150**	**147**	**148**	**295**
Health Assessment Questionnaire (HAQ) Score at Week 24 [units: scores on a scale]	**0.0000 (-0.2500 to 0.2500)**	**0.1250 (0.0000 to 0.5000)**	**0.2500 (0.0000 to 0.5000)**	**0.2500 (0.0000 to 0.5000)**

Median (Inter-Quartile Range)				

Statistical Analysis 1 for Health Assessment Questionnaire (HAQ) Score at Week 24

Groups [1]	Group 1: Placebo vs. Combined Golimumab
Method [2]	ANOVA on van der Waerden normal scores.
P Value [3]	<0.001

[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:
	Stratified by baseline Methotrexate (MTX).
[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 Health Assessment Questionnaire (HAQ) Score at Week 24

Groups [1]	Group 1: Placebo vs. Group 2: Golimumab 50 mg
Method [2]	ANOVA on van der Waerden normal scores.
P Value [3]	<0.001

[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:
	Stratified by baseline MTX.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Test was performed because Group 1: Placebo was significantly different from Combined Groups 2 & 3.

Statistical Analysis 3 for Health Assessment Questionnaire (HAQ) Score at Week 24

Groups [1]	Group 1: Placebo vs. Group 3: Golimumab 100 mg
Method [2]	ANOVA on van der Waerden normal scores.
P Value [3]	<0.001

[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:
	Stratified by baseline MTX.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Test was performed because Group 1: Placebo was significantly different from Combined Groups 2 & 3.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse event data were collected for 5 years
Additional Description	Only participants who received at least 1 dose of golimumab were included in the safety analysis. The total number of participants at risk for adverse events is therefore less than the number of participants who started the study.

Reporting Groups

	Description
Group 1: Golimumab 50 mg SC Injections Only	Participants who were treated with golimumab and received golimumab 50 mg injections only during the study.
Group 2: Golimumab 100 mg SC Injections Only	Participants who were treated with golimumab and received golimumab 100 mg injections only during the study.
Group 3: Golimumab 50 and 100 mg SC Injections	Participants who were treated with golimumab and received at least one injection of both golimumab 50 mg and golimumab 100 mg during the study.

Serious Adverse Events

	Group 1: Golimumab 50 mg SC Injections Only	Group 2: Golimumab 100 mg SC Injections Only	Group 3: Golimumab 50 and 100 mg SC Injections
Total, serious adverse events			
# participants affected / at risk	**34/98 (34.69%)**	**46/138 (33.33%)**	**71/195 (36.41%)**
Blood and lymphatic system disorders			
Pancytopenia † [1]			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Thrombocytopenia † [1]			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Cardiac disorders			
Acute Coronary Syndrome † [1]			

# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	2/195 (1.03%)
Acute Myocardial Infarction † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Angina Pectoris † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	1/195 (0.51%)
Aortic Valve Incompetence † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Atrial Fibrillation † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	2/195 (1.03%)
Atrial Flutter † 1			
# participants affected / at risk	1/98 (1.02%)	0/138 (0.00%)	0/195 (0.00%)
Cardiac Failure Congestive † 1			
# participants affected / at risk	0/98 (0.00%)	2/138 (1.45%)	0/195 (0.00%)
Cardiomyopathy † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Cardiovascular Disorder † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Coronary Artery Disease † 1			
# participants affected / at risk	1/98 (1.02%)	0/138 (0.00%)	1/195 (0.51%)
Myocardial Infarction † 1			
# participants affected / at risk	0/98 (0.00%)	2/138 (1.45%)	0/195 (0.00%)
Sick Sinus Syndrome † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)

Supraventricular Tachycardia † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Tachycardia † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Torsade De Pointes † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Congenital, familial and genetic disorders			
Branchial Cleft Cyst † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Endocrine disorders			
Adrenal Insufficiency † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Gastrointestinal disorders			
Abdominal Pain † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Colitis † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**2/195 (1.03%)**
Colitis Ulcerative † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Colonic Polyp † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Diarrhoea † 1			

# participants affected / at risk	1/98 (1.02%)	0/138 (0.00%)	1/195 (0.51%)
Diverticulum Intestinal † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Gastric Polyps † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Gastritis † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	2/195 (1.03%)
Gastritis Erosive † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Gastrointestinal Disorder † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Inguinal Hernia † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Large Intestine Perforation † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Nausea † 1			
# participants affected / at risk	1/98 (1.02%)	0/138 (0.00%)	0/195 (0.00%)
Oesophagitis † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Pancreatitis † 1			
# participants affected / at risk	0/98 (0.00%)	2/138 (1.45%)	0/195 (0.00%)
Rectal Haemorrhage † 1			
# participants affected / at risk	1/98 (1.02%)	0/138 (0.00%)	0/195 (0.00%)

Small Intestinal Obstruction † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**1/195 (0.51%)**
Splenic Artery Aneurysm † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Varices Oesophageal † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Vomiting † 1			
# participants affected / at risk	**2/98 (2.04%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
General disorders			
Chest Pain † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Device Breakage † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Device Dislocation † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Device Failure † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Generalised Oedema † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Hernia † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Multi-Organ Failure † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**

Non-Cardiac Chest Pain † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Pain † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Pyrexia † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**1/195 (0.51%)**
Hepatobiliary disorders			
Bile Duct Stone † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Biliary Cirrhosis Primary † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Cholecystitis † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Cholecystitis Acute † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Cholecystitis Chronic † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Cholelithiasis † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**1/195 (0.51%)**
Drug-Induced Liver Injury † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Infections and infestations			
Abdominal Abscess † 1			

# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	1/195 (0.51%)
Appendicitis † 1			
# participants affected / at risk	1/98 (1.02%)	0/138 (0.00%)	0/195 (0.00%)
Bacteraemia † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Bronchitis † 1			
# participants affected / at risk	1/98 (1.02%)	0/138 (0.00%)	0/195 (0.00%)
Cellulitis † 1			
# participants affected / at risk	1/98 (1.02%)	1/138 (0.72%)	2/195 (1.03%)
Cellulitis Streptococcal † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Diverticulitis † 1			
# participants affected / at risk	0/98 (0.00%)	2/138 (1.45%)	2/195 (1.03%)
Erysipelas † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Extradural Abscess † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	1/195 (0.51%)
Gastroenteritis † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	2/195 (1.03%)
Gastroenteritis Salmonella † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Herpes Zoster † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)

Histoplasmosis † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Histoplasmosis Disseminated † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Infected Skin Ulcer † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Infection † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**2/195 (1.03%)**
Intervertebral Discitis † 1			
# participants affected / at risk	**1/98 (1.02%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Lung Infection Pseudomonal † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Osteomyelitis † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Pelvic Abscess † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Periorbital Cellulitis † 1			
# participants affected / at risk	**1/98 (1.02%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Pneumonia † 1			
# participants affected / at risk	**3/98 (3.06%)**	**5/138 (3.62%)**	**10/195 (5.13%)**
Post Procedural Infection † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Pulmonary Tuberculosis † 1			

# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Pyelonephritis † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Salpingitis † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Sepsis † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	5/195 (2.56%)
Staphylococcal Abscess † 1			
# participants affected / at risk	1/98 (1.02%)	1/138 (0.72%)	0/195 (0.00%)
Staphylococcal Infection † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Subcutaneous Abscess † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	1/195 (0.51%)
Tracheobronchitis † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Upper Respiratory Tract Infection † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Urinary Tract Infection † 1			
# participants affected / at risk	0/98 (0.00%)	2/138 (1.45%)	5/195 (2.56%)
Urosepsis † 1			
# participants affected / at risk	2/98 (2.04%)	0/138 (0.00%)	0/195 (0.00%)
Injury, poisoning and procedural complications			

Ankle Fracture † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Concussion † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Contusion † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Femoral Neck Fracture † 1			
# participants affected / at risk	**1/98 (1.02%)**	**1/138 (0.72%)**	**1/195 (0.51%)**
Femur Fracture † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**1/195 (0.51%)**
Fractured Sacrum † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**1/195 (0.51%)**
Hip Fracture † 1			
# participants affected / at risk	**1/98 (1.02%)**	**1/138 (0.72%)**	**1/195 (0.51%)**
Humerus Fracture † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Lower Limb Fracture † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Meniscus Lesion † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Muscle Rupture † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Open Fracture † 1			

# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Pelvic Fracture † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Pubis Fracture † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Stress Fracture † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Wound Dehiscence † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Metabolism and nutrition disorders			
Dehydration † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	1/195 (0.51%)
Diabetic Ketoacidosis † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Hyponatraemia † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	1/98 (1.02%)	2/138 (1.45%)	1/195 (0.51%)
Arthritis † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	1/195 (0.51%)
Back Pain † 1			

# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	1/195 (0.51%)
Bone Disorder † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Bursitis † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Compartment Syndrome † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Intervertebral Disc Protrusion † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Joint Effusion † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Joint Swelling † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Lumbar Spinal Stenosis † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Mobility Decreased † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Neck Pain † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Osteoarthritis † 1			
# participants affected / at risk	2/98 (2.04%)	1/138 (0.72%)	8/195 (4.10%)
Osteonecrosis † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	2/195 (1.03%)

Osteoporosis † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Pain in Extremity † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Rheumatoid Arthritis † 1			
# participants affected / at risk	**4/98 (4.08%)**	**2/138 (1.45%)**	**8/195 (4.10%)**
Rheumatoid Nodule † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Rotator Cuff Syndrome † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Scleroderma † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Spinal Column Stenosis † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**1/195 (0.51%)**
Spondylolisthesis † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Synovitis † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Tenosynovitis † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-Cell Lymphoma † 1			

# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**1/195 (0.51%)**
Basal Cell Carcinoma † 1			
# participants affected / at risk	**0/98 (0.00%)**	**3/138 (2.17%)**	**1/195 (0.51%)**
Breast Cancer † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**1/195 (0.51%)**
Cervix Carcinoma † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Diffuse Large B-Cell Lymphoma † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Leukaemia † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Lung Carcinoma Cell Type Unspecified Stage Iv † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Lymphoma † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Pancreatic Carcinoma † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Rectal Cancer † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Squamous Cell Carcinoma † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**2/195 (1.03%)**
Squamous Cell Carcinoma of Skin † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**

Thyroid Adenoma † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Urinary Tract Neoplasm † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Nervous system disorders			
Carpal Tunnel Syndrome † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**2/195 (1.03%)**
Cerebrovascular Accident † 1			
# participants affected / at risk	**1/98 (1.02%)**	**3/138 (2.17%)**	**1/195 (0.51%)**
Cervicobrachial Syndrome † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Convulsion † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Demyelination † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**1/195 (0.51%)**
Hypoaesthesia † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Migraine † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Neuralgia † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Paraesthesia † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**

Presyncope † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Sciatica † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Syncope † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Transient Ischaemic Attack † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Viith Nerve Paralysis † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Psychiatric disorders			
Depression † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Mental Status Changes † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Renal and urinary disorders			
Calculus Urinary † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Renal Disorder † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Renal Failure † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Renal Failure Acute † 1			

# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Renal Tubular Necrosis † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Vesical Fistula † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Reproductive system and breast disorders			
Endometriosis † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Female Genital Tract Fistula † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Uterine Haemorrhage † 1			
# participants affected / at risk	1/98 (1.02%)	0/138 (0.00%)	0/195 (0.00%)
Respiratory, thoracic and mediastinal disorders			
Alveolitis † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Asthma † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	1/195 (0.51%)
Dyspnoea † 1			
# participants affected / at risk	0/98 (0.00%)	2/138 (1.45%)	1/195 (0.51%)
Mediastinal Mass † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Pleural Fibrosis † 1			

# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	1/195 (0.51%)
Pleurisy † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	1/195 (0.51%)
Pneumonitis † 1			
# participants affected / at risk	1/98 (1.02%)	1/138 (0.72%)	0/195 (0.00%)
Pulmonary Embolism † 1			
# participants affected / at risk	1/98 (1.02%)	2/138 (1.45%)	1/195 (0.51%)
Pulmonary Hypertension † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Skin and subcutaneous tissue disorders			
Psoriasis † 1			
# participants affected / at risk	0/98 (0.00%)	1/138 (0.72%)	0/195 (0.00%)
Surgical and medical procedures			
Drug Detoxification † 1			
# participants affected / at risk	1/98 (1.02%)	0/138 (0.00%)	0/195 (0.00%)
Vascular disorders			
Aortic Thrombosis † 1			
# participants affected / at risk	1/98 (1.02%)	0/138 (0.00%)	0/195 (0.00%)
Deep Vein Thrombosis † 1			
# participants affected / at risk	0/98 (0.00%)	3/138 (2.17%)	0/195 (0.00%)
Haematoma † 1			
# participants affected / at risk	0/98 (0.00%)	0/138 (0.00%)	2/195 (1.03%)

Haemorrhage † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Hypertension † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**2/195 (1.03%)**
Hypotension † 1			
# participants affected / at risk	**0/98 (0.00%)**	**1/138 (0.72%)**	**0/195 (0.00%)**
Labile Blood Pressure † 1			
# participants affected / at risk	**1/98 (1.02%)**	**0/138 (0.00%)**	**0/195 (0.00%)**
Orthostatic Hypotension † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**
Subclavian Artery Stenosis † 1			
# participants affected / at risk	**0/98 (0.00%)**	**0/138 (0.00%)**	**1/195 (0.51%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA Version 15.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse event data were collected for 5 years
Additional Description	Only participants who received at least 1 dose of golimumab were included in the safety analysis. The total number of participants at risk for adverse events is therefore less than the number of participants who started the study.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Group 1: Golimumab 50 mg SC Injections Only	Participants who were treated with golimumab and received golimumab 50 mg injections only during the study.
Group 2: Golimumab 100 mg SC Injections Only	Participants who were treated with golimumab and received golimumab 100 mg injections only during the study.
Group 3: Golimumab 50 and 100 mg SC Injections	Participants who were treated with golimumab and received at least one injection of both golimumab 50 mg and golimumab 100 mg during the study.

Other Adverse Events

	Group 1: Golimumab 50 mg SC Injections Only	Group 2: Golimumab 100 mg SC Injections Only	Group 3: Golimumab 50 and 100 mg SC Injections
Total, other (not including serious) adverse events			
# participants affected / at risk	**76/98 (77.55%)**	**117/138 (84.78%)**	**172/195 (88.21%)**
Ear and labyrinth disorders			
Vertigo † [1]			
# participants affected / at risk	**5/98 (5.10%)**	**4/138 (2.90%)**	**4/195 (2.05%)**
Eye disorders			
Dry Eye † [1]			
# participants affected / at risk	**5/98 (5.10%)**	**4/138 (2.90%)**	**5/195 (2.56%)**

Gastrointestinal disorders			
Diarrhoea † 1			
# participants affected / at risk	**4/98 (4.08%)**	**22/138 (15.94%)**	**28/195 (14.36%)**
Gastrooesophageal Reflux Disease † 1			
# participants affected / at risk	**1/98 (1.02%)**	**6/138 (4.35%)**	**10/195 (5.13%)**
Nausea † 1			
# participants affected / at risk	**9/98 (9.18%)**	**18/138 (13.04%)**	**21/195 (10.77%)**
Vomiting † 1			
# participants affected / at risk	**3/98 (3.06%)**	**12/138 (8.70%)**	**7/195 (3.59%)**
General disorders			
Fatigue † 1			
# participants affected / at risk	**2/98 (2.04%)**	**16/138 (11.59%)**	**16/195 (8.21%)**
Injection Site Erythema † 1			
# participants affected / at risk	**6/98 (6.12%)**	**13/138 (9.42%)**	**18/195 (9.23%)**
Oedema Peripheral † 1			
# participants affected / at risk	**3/98 (3.06%)**	**10/138 (7.25%)**	**11/195 (5.64%)**
Pyrexia † 1			
# participants affected / at risk	**2/98 (2.04%)**	**4/138 (2.90%)**	**10/195 (5.13%)**

Immune system disorders			
Seasonal Allergy † 1			
# participants affected / at risk	**2/98 (2.04%)**	**9/138 (6.52%)**	**2/195 (1.03%)**
Infections and infestations			
Bronchitis † 1			
# participants affected / at risk	**11/98 (11.22%)**	**22/138 (15.94%)**	**24/195 (12.31%)**
Ear Infection † 1			
# participants affected / at risk	**2/98 (2.04%)**	**7/138 (5.07%)**	**8/195 (4.10%)**
Influenza † 1			
# participants affected / at risk	**4/98 (4.08%)**	**7/138 (5.07%)**	**15/195 (7.69%)**
Nasopharyngitis † 1			
# participants affected / at risk	**10/98 (10.20%)**	**26/138 (18.84%)**	**37/195 (18.97%)**
Oral Herpes † 1			
# participants affected / at risk	**6/98 (6.12%)**	**9/138 (6.52%)**	**7/195 (3.59%)**
Pneumonia † 1			
# participants affected / at risk	**2/98 (2.04%)**	**7/138 (5.07%)**	**6/195 (3.08%)**
Rhinitis † 1			
# participants affected / at risk	**2/98 (2.04%)**	**9/138 (6.52%)**	**2/195 (1.03%)**

Sinusitis † 1			
# participants affected / at risk	**19/98 (19.39%)**	**23/138 (16.67%)**	**35/195 (17.95%)**
Upper Respiratory Tract Infection † 1			
# participants affected / at risk	**25/98 (25.51%)**	**43/138 (31.16%)**	**49/195 (25.13%)**
Urinary Tract Infection † 1			
# participants affected / at risk	**13/98 (13.27%)**	**12/138 (8.70%)**	**22/195 (11.28%)**
Viral Infection † 1			
# participants affected / at risk	**2/98 (2.04%)**	**7/138 (5.07%)**	**4/195 (2.05%)**
Injury, poisoning and procedural complications			
Contusion † 1			
# participants affected / at risk	**2/98 (2.04%)**	**8/138 (5.80%)**	**12/195 (6.15%)**
Excoriation † 1			
# participants affected / at risk	**3/98 (3.06%)**	**6/138 (4.35%)**	**10/195 (5.13%)**
Laceration † 1			
# participants affected / at risk	**2/98 (2.04%)**	**7/138 (5.07%)**	**14/195 (7.18%)**
Investigations			
Alanine Aminotransferase			

Increased † 1			
# participants affected / at risk	6/98 (6.12%)	0/138 (0.00%)	5/195 (2.56%)
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	12/98 (12.24%)	20/138 (14.49%)	25/195 (12.82%)
Back Pain † 1			
# participants affected / at risk	8/98 (8.16%)	17/138 (12.32%)	36/195 (18.46%)
Bursitis † 1			
# participants affected / at risk	4/98 (4.08%)	6/138 (4.35%)	10/195 (5.13%)
Joint Swelling † 1			
# participants affected / at risk	1/98 (1.02%)	8/138 (5.80%)	3/195 (1.54%)
Muscle Spasms † 1			
# participants affected / at risk	1/98 (1.02%)	12/138 (8.70%)	6/195 (3.08%)
Musculoskeletal Pain † 1			
# participants affected / at risk	2/98 (2.04%)	9/138 (6.52%)	15/195 (7.69%)
Osteoarthritis † 1			
# participants affected / at risk	3/98 (3.06%)	5/138 (3.62%)	13/195 (6.67%)

Pain in Extremity † 1			
# participants affected / at risk	**4/98 (4.08%)**	**9/138 (6.52%)**	**16/195 (8.21%)**
Rheumatoid Arthritis † 1			
# participants affected / at risk	**14/98 (14.29%)**	**23/138 (16.67%)**	**53/195 (27.18%)**
Tendonitis † 1			
# participants affected / at risk	**4/98 (4.08%)**	**12/138 (8.70%)**	**16/195 (8.21%)**
Nervous system disorders			
Dizziness † 1			
# participants affected / at risk	**4/98 (4.08%)**	**8/138 (5.80%)**	**10/195 (5.13%)**
Headache † 1			
# participants affected / at risk	**14/98 (14.29%)**	**14/138 (10.14%)**	**19/195 (9.74%)**
Hypoaesthesia † 1			
# participants affected / at risk	**2/98 (2.04%)**	**8/138 (5.80%)**	**5/195 (2.56%)**
Paraesthesia † 1			
# participants affected / at risk	**4/98 (4.08%)**	**8/138 (5.80%)**	**11/195 (5.64%)**
Psychiatric disorders			
Anxiety † 1			
# participants affected / at risk	**1/98 (1.02%)**	**12/138 (8.70%)**	**11/195 (5.64%)**

Depression † 1			
# participants affected / at risk	**3/98 (3.06%)**	**8/138 (5.80%)**	**18/195 (9.23%)**
Insomnia † 1			
# participants affected / at risk	**0/98 (0.00%)**	**11/138 (7.97%)**	**11/195 (5.64%)**
Respiratory, thoracic and mediastinal disorders			
Cough † 1			
# participants affected / at risk	**10/98 (10.20%)**	**13/138 (9.42%)**	**24/195 (12.31%)**
Oropharyngeal Pain † 1			
# participants affected / at risk	**4/98 (4.08%)**	**8/138 (5.80%)**	**15/195 (7.69%)**
Skin and subcutaneous tissue disorders			
Rash † 1			
# participants affected / at risk	**4/98 (4.08%)**	**8/138 (5.80%)**	**19/195 (9.74%)**
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**10/98 (10.20%)**	**17/138 (12.32%)**	**34/195 (17.44%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA Version 15.0

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
The count of patients with any nonserious adverse events (NAE) excludes patients who only had NAE that occurred in <= 5% of patients. This information may vary from existing approved labeling and publications due to the requirement of this website.

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:** Generally, the only disclosure restriction on the PI is that the sponsor has 60 days to review results communications prior to public release and can embargo communications regarding trial results for a period that does not exceed 180 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend

the embargo.

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Smolen JS, Kay J, Doyle M, Landewé R, Matteson EL, Gaylis N, Wollenhaupt J, Murphy FT, Xu S, Zhou Y, Hsia EC. Golimumab in patients with active rheumatoid arthritis after treatment with tumor necrosis factor α inhibitors: findings with up to five years of treatment in the multicenter, randomized, double-blind, placebo-controlled, phase 3 GO-AFTER study. Arthritis Res Ther. 2015 Jan 22;17:14. doi: 10.1186/s13075-015-0516-6.

Smolen JS, Kay J, Doyle MK, Landewé R, Matteson EL, Wollenhaupt J, Gaylis N, Murphy FT, Neal JS, Zhou Y, Visvanathan S, Hsia EC, Rahman MU; GO-AFTER study investigators. Golimumab in patients with active rheumatoid arthritis after treatment with tumour necrosis factor alpha inhibitors (GO-AFTER study): a multicentre, randomised, double-blind, placebo-controlled, phase III trial. Lancet. 2009 Jul 18;374(9685):210-21. doi: 10.1016/S0140-6736(09)60506-7. Epub 2009 Jun 26. Erratum in: Lancet. 2009 Oct 24;374(9699):1422.

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