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Trial record **1 of 1** for: C0524T09

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A Study of the Safety and Efficacy of Golimumab in Subjects With Active Ankylosing Spondylitis

This study has been completed.

Sponsor:
Centocor, Inc.

Collaborator:
Schering-Plough

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

ClinicalTrials.gov Identifier:
NCT00265083

First received: December 12, 2005
Last updated: July 12, 2013
Last verified: July 2013
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:	Spondylitis, Ankylosing
Interventions:	Biological: golimumab Biological: Golimumab (CNTO 148); 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
356 patients were randomly assigned to treatment groups at 42 sites (17 in North America, 16 in Europe and 9 in Asia). Consent was obtained from the first patient on 13 Dec 2005. The last patient completed the final visit of the 24-week reporting period on 15 May 2007. The last patient completed the final visit of the 5-year period on 17 Jan 2012.

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 SC injections every 4 weeks (wks) from Week (Wk) 0 thru Wk 20 (unless early escape at Wk 16); golimumab - if early escape, 50 mg SC every 4 wks from Wk 16 up to 5 yrs; golimumab - 50 mg SC beginning Wk 24 up to 5 yrs (unless early escape); golimumab- Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group 2: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 thru 5 yrs (unless early escape at Wk 16); golimumab - If early escape, 100 mg SC every 4 wks beginning Wk 16 up to 5 yrs; golimumab - Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group 3: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs.

Participant Flow: Overall Study

	Group 1: Placebo	Group 2: Golimumab 50 mg	Group 3: Golimumab 100 mg

STARTED	**78**	**138** [1]	**140**
COMPLETED	**61**	**96** [1]	**98**
NOT COMPLETED	**17**	**42**	**42**
Adverse Event	**5**	**13**	**15**
Lost to Follow-up	**3**	**4**	**4**
Unsatisfactory therapeutic effect	**8**	**13**	**14**
Not specified	**1**	**12**	**9**

[1] One patient did not receive study agent.

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 I: Placebo	Placebo SC injections every 4 weeks (wks) from Week (Wk) 0 thru Wk 20 (unless early escape at Wk 16); golimumab - if early escape, 50 mg SC every 4 wks from Wk 16 up to 5 yrs; golimumab - 50 mg SC beginning Wk 24 up to 5 yrs (unless early escape); golimumab- Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group II: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 thru 5 yrs (unless early escape at Wk 16); golimumab - If early escape, 100 mg SC every 4 wks beginning Wk 16 up to 5 yrs; golimumab - Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group III: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs.
Total	Total of all reporting groups

Baseline Measures

	Group I: Placebo	**Group II: Golimumab 50 mg**	**Group III: Golimumab 100 mg**	**Total**
Number of Participants [units: participants]	**78**	**138**	**140**	**356**
Age [units: years] Mean (Standard Deviation)	**40.6 (12.71)**	**39.2 (12.46)**	**38.6 (11.30)**	**39.3 (12.06)**
Gender [units: participants]				
Female	**23**	**36**	**42**	**101**
Male	**55**	**102**	**98**	**255**

Outcome Measures

Hide All Outcome Measures

1. Primary: Assessment in Ankylosing Spondylitis 20 Responders at Week 14 [Time Frame: Week 14]

Measure Type	Primary
Measure Title	Assessment in Ankylosing Spondylitis 20 Responders at Week 14
Measure Description	Number of patients who achieved a 20% improvement and at least 1 absolute improvement on a 0 to 10 cm scale from baseline to Week 14 in at least 3 of the 4 domains: patient global, total back pain, function or inflammation.
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.
Intent to treat (ITT). Patients considered non-responder if used any pre-specified prohibited medications or discontinued subcutaneous (SC) study agent due to lack of efficacy. Missing ASAS components at Week 14 were imputed by Last Observation Carried Forward (LOCF) unless all ASAS components are missing in which case considered non-responders.

Reporting Groups

	Description
Group I: Placebo	Placebo SC injections every 4 weeks (wks) from Week (Wk) 0 thru Wk 20 (unless early escape at Wk 16); golimumab - if early escape, 50 mg SC every 4 wks from Wk 16 up to 5 yrs; golimumab - 50 mg SC beginning Wk 24 up to 5 yrs (unless early escape); golimumab- Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group II: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 thru 5 yrs (unless early escape at Wk 16); golimumab - If early escape, 100 mg SC every 4 wks beginning Wk 16 up to 5 yrs; golimumab - Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group III: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs.
Combined: Groups II & III	Combines Group II (golimumab 50 mg) and Group III (golimumab 100 mg).

Measured Values

	Group I: Placebo	**Group II: Golimumab 50 mg**	**Group III: Golimumab 100 mg**	**Combined: Groups II & III**
Number of Participants Analyzed [units: participants]	**78**	**138**	**140**	**278**
Assessment in Ankylosing Spondylitis 20 Responders at Week 14 [units: Participants]	**17**	**82**	**84**	**166**

Statistical Analysis 1 for Assessment in Ankylosing Spondylitis 20 Responders at Week 14

Groups [1]	Group I: Placebo vs. Combined: Groups II & III
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 ASAS 20 response comparing Groups I vs II and Groups I vs III. The sample size of 75 patients (pts) in placebo and 135 pts per active group will provide >=99% power to detect a difference in ASAS 20 response between treatment groups at alpha=0.05, assuming 50% of pts with screening CRP<1.5mg/dL, and the difference in ASAS 20 response of 10-27.5% in pts with screening CRP<1.5mg/dL and 32.5-45% in pts with screening CRP>=1.5mg/dL, between Groups I vs II or III.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Cochran-Mantel-Haenszel with stratification: screening CRP level (<=1.5mg/dL, >1.5mg/dL)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The positive test is defined if the comparison between combined golimumab and placebo is significant (p-value <0.05), and at least one of the pair-wise comparisons is also significant (p-value <0.05).

Statistical Analysis 2 for Assessment in Ankylosing Spondylitis 20 Responders at Week 14

Groups [1]	Group I: Placebo vs. Group II: 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:

	Cochran-Mantel-Haenszel with stratification: screening CRP level (<=1.5mg/dL, >1.5mg/dL)
[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 3 for Assessment in Ankylosing Spondylitis 20 Responders at Week 14

Groups [1]	Group I: Placebo vs. Group III: 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:
	Cochran-Mantel-Haenszel with stratification: screening CRP level (<=1.5mg/dL, >1.5mg/dL)
[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: Assessment in Ankylosing Spondylitis 20 Responders at Week 24 [Time Frame: Week 24]

Measure Type	Secondary
Measure Title	Assessment in Ankylosing Spondylitis 20 Responders at Week 24
Measure Description	Number of patients who achieved a 20% improvement and at least 1 absolute improvement on a 0 to 10 cm scale from baseline to Week 24 at least 3 of the 4 domains: patient global, total back pain, function or inflammation.
Time Frame	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.
ITT. Patients (pts) considered non-responder if used any pre-specified prohibited medications or discontinued SC study agent due to lack of efficacy. Missing ASAS components were imputed by LOCF unless all ASAS components are missing in which case considered non-responders. Wk 16 ASAS response was used for pts with change in study treatment.

Reporting Groups

	Description
Group I: Placebo	Placebo SC injections every 4 weeks (wks) from Week (Wk) 0 thru Wk 20 (unless early escape at Wk 16); golimumab - if early escape, 50 mg SC every 4 wks from Wk 16 up to 5 yrs; golimumab - 50 mg SC beginning Wk 24 up to 5 yrs (unless early escape); golimumab- Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group II: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 thru 5 yrs (unless early escape at Wk 16); golimumab - If early escape, 100 mg SC every 4 wks beginning Wk 16 up to 5 yrs; golimumab - Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group III: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs.
Combined: Groups II & III	Combines Group II (golimumab 50 mg) and Group III (golimumab 100 mg).

Measured Values

	Group I: Placebo	Group II: Golimumab 50 mg	Group III: Golimumab 100 mg	Combined: Groups II & III
Number of Participants Analyzed [units: participants]	**78**	**138**	**140**	**278**
Assessment in Ankylosing Spondylitis 20 Responders at Week 24	**18**	**77**	**92**	**169**

[units: P a r t i c ip an t s]				

Statistical Analysis 1 for Assessment in Ankylosing Spondylitis 20 Responders at Week 24

Groups [1]	Group I: Placebo vs. Combined: Groups II & III
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 ASAS 20 response comparing Groups I vs. II and Groups I vs. III.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Cochran-Mantel-Haenszel with stratification: screening CRP level (<=1.5mg/dL, >1.5mg/dL)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The positive test is defined if the comparison between combined golimumab and placebo is significant (p-value <0.05), and at least one of the pair-wise comparisons is also significant (p-value <0.05).

Statistical Analysis 2 for Assessment in Ankylosing Spondylitis 20 Responders at Week 24

Groups [1]	Group I: Placebo vs. Group II: 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 ASAS 20 response between Group II and Group I.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Cochran-Mantel-Haenszel with stratification: screening CRP level (<=1.5mg/dL, >1.5mg/dL)
[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 3 for Assessment in Ankylosing Spondylitis 20 Responders at Week 24

Groups [1]	Group I: Placebo vs. Group III: 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 ASAS 20 response between Group III and Group I.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Cochran-Mantel-Haenszel with stratification: screening CRP level (<=1.5mg/dL, >1.5mg/dL)
[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: Summary of Change From Baseline in Bath Ankylosing Spondylitis Functional Index at Week 14 [Time Frame: From Baseline to Week 14]

Measure Type	Secondary
Measure Title	Summary of Change From Baseline in Bath Ankylosing Spondylitis Functional Index at Week 14
Measure Description	

	The Bath Ankylosing Spondylitis Functional Index (BASFI) is calculated as the mean of 10 VAS, each of length 0 to 10 cm. Eight of the scales relate to functional capacity of patients while the other 2 relate to a patient's ability to cope with everyday life. Change from baseline is Wk 14 value minus baseline value.
Time Frame	From Baseline to 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.
Intent to treat (ITT). Patients considered non-change from baseline in BASFI if used any pre-specified prohibited medications or discontinued SC study agent due to lack of efficacy. Missing value of change from baseline in BASFI at Week 14 was imputed by Last Observation Carried Forward (LOCF).

Reporting Groups

	Description
Group I: Placebo	Placebo SC injections every 4 weeks (wks) from Week (Wk) 0 thru Wk 20 (unless early escape at Wk 16); golimumab - if early escape, 50 mg SC every 4 wks from Wk 16 up to 5 yrs; golimumab - 50 mg SC beginning Wk 24 up to 5 yrs (unless early escape); golimumab- Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group II: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 thru 5 yrs (unless early escape at Wk 16); golimumab - If early escape, 100 mg SC every 4 wks beginning Wk 16 up to 5 yrs; golimumab - Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group III: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs.
Combined: Groups II & III	Combines Group II (golimumab 50 mg) and Group III (golimumab 100 mg).

Measured Values

	Group I: Placebo	**Group II: Golimumab 50 mg**	**Group III: Golimumab 100 mg**	**Combined: Groups II & III**
Number of Participants Analyzed [units: participants]	**78**	**138**	**140**	**278**
Summary of Change From Baseline in Bath Ankylosing Spondylitis Functional Index at Week 14 [units: Change from baseline in BASFI Index] Median (Inter-Quartile Range)	**0.095 (-1.050 to 1.120)**	**-1.375 (-3.130 to -0.120)**	**-1.495 (-2.985 to -0.060)**	**-1.420 (-3.070 to -0.080)**

Statistical Analysis 1 for Summary of Change From Baseline in Bath Ankylosing Spondylitis Functional Index at Week 14

Groups [1]	Group I: Placebo vs. Combined: Groups II & III
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:
	Null hypothesis: No difference in change from baseline in BASFI comparing Groups I vs. II and Groups I vs. III.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANOVA on van der Waerden normal scores with 2 factors: treatment group and screening C-reactive protein (CRP) level.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The positive test is defined if the comparison between combined golimumab and placebo is significant (p-value <0.05), and at least one of the pair-wise comparisons is also significant (p-value <0.05).

Statistical Analysis 2 for Summary of Change From Baseline in Bath Ankylosing Spondylitis Functional Index at Week 14

Groups [1]	Group I: Placebo vs. Group II: 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:
	Null hypothesis: no difference in BASFI between Group II and Group I.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANOVA on van der Waerden normal scores with 2 factors: treatment group and screening C-reactive protein (CRP) level.
[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 3 for Summary of Change From Baseline in Bath Ankylosing Spondylitis Functional Index at Week 14

Groups [1]	Group I: Placebo vs. Group III: 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:
	Null hypothesis: no difference in BASFI between Group III and Group I.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANOVA on van der Waerden normal scores with 2 factors: treatment group and screening C-reactive protein (CRP) level.
[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: Summary of Change From Baseline in Bath Ankylosing Spondylitis Metrology Index at Week 14 [Time Frame: From Baseline to Week 14]

Measure Type	Secondary
Measure Title	Summary of Change From Baseline in Bath Ankylosing Spondylitis Metrology Index at Week 14
Measure Description	The Bath Ankylosing Spondylitis Metrology Index (BASMI) is the sum of scores comprised of 5 measures (0=mild, 1=moderate & 2=severe): Tragus-to-wall; Lumbar flexion; Cervical rotation; Lumbar side flexion; Intermalleolar distance. BASMI ranges from 0 to 10. Change from baseline is Wk 14 value minus baseline value.
Time Frame	From Baseline to 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.
Intent to treat (ITT). Patients considered non-change from baseline in BASMI if used any pre-specified prohibited medications or discontinued SC study agent due to lack of efficacy. Missing value of change from baseline in BASMI at Week 14 was imputed by Last Observation Carried Forward (LOCF).

Reporting Groups

	Description
Group I: Placebo	Placebo SC injections every 4 weeks (wks) from Week (Wk) 0 thru Wk 20 (unless early escape at Wk 16); golimumab - if early escape, 50 mg SC every 4 wks from Wk 16 up to 5 yrs; golimumab - 50 mg SC beginning Wk 24 up to 5 yrs (unless early escape); golimumab- Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group II: Golimumab 50 mg	Golimumab 50 mg SC injections every 4 wks from Wk 0 thru 5 yrs (unless early escape at Wk 16); golimumab - If early escape, 100 mg SC every 4 wks beginning Wk 16 up to 5 yrs; golimumab - Dr's discretion after unblinding, dose adjust from 50 to 100 mg.
Group III: Golimumab 100 mg	Golimumab 100 mg SC injections every 4 wks from Wk 0 up to 5 yrs.
Combined: Groups II & III	Combines Group II (golimumab 50 mg) and Group III (golimumab 100 mg).

Measured Values

	Group I: Placebo	Group II: Golimumab 50 mg	Group III: Golimumab 100 mg	Combined: Groups II & III
Number of Participants Analyzed [units: participants]	**78**	**138**	**140**	**278**
Summary of Change From Baseline in Bath Ankylosing Spondylitis Metrology Index at Week 14 [units: Change from baseline in BASMI Index] Mean (Standard Deviation)	**-0.28 (1.015)**	**-0.36 (1.112)**	**-0.49 (1.296)**	**-0.43 (1.208)**

Statistical Analysis 1 for Summary of Change From Baseline in Bath Ankylosing Spondylitis Metrology Index at Week 14

Groups [1]	Group I: Placebo vs. Combined: Groups II & III
Method [2]	ANOVA on van der Waerden normal scores
P Value [3]	0.288

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null hypothesis: No difference in change from baseline in BASMI comparing Groups I vs. II and Groups I vs. III.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANOVA on van der Waerden normal scores with 2 factors: treatment group and screening C-reactive protein (CRP) level.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The positive test is defined if the comparison between combined golimumab and placebo is significant at the 0.05, and at least one of the pair-wise comparisons is also significant at the 0.05.

Statistical Analysis 2 for Summary of Change From Baseline in Bath Ankylosing Spondylitis Metrology Index at Week 14

Groups [1]	Group I: Placebo vs. Group II: Golimumab 50 mg
Method [2]	ANOVA on van der Waerden normal scores
P Value [3]	0.444

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null hypothesis: no difference in BASMI between Group II and Group I.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANOVA on van der Waerden normal scores with 2 factors: treatment group and screening C-reactive protein (CRP) level.
[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 3 for Summary of Change From Baseline in Bath Ankylosing Spondylitis Metrology Index at Week 14

Groups [1]	Group I: Placebo vs. Group III: Golimumab 100 mg
Method [2]	ANOVA on van der Waerden normal scores
P Value [3]	0.247

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null hypothesis: no difference in BASMI between Group III and Group I.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANOVA on van der Waerden normal scores with 2 factors: treatment group and screening C-reactive protein (CRP) level.
[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	Up to 5 years (end of study)
Additional Description	The number of participants reported at risk for adverse events (AEs) in each treatment (tx) group is based on actual tx received during the study and may differ from the number of participants who started tx in the study. Participants may be counted more than once in the analysis of AEs if they received tx at more than one dose level in the study.

Reporting Groups

	Description
Group 1: Golimumab 50 mg	Subjects who were treated with Golimumab and received Golimumab 50 mg injections only.
Group 2: Golimumab 100 mg	Subjects who were treated with Golimumab and received Golimumab 100 mg injections only.
Group 3: Golimumab 50 and 100 mg	Subjects who were treated with Golimumab and received at least one injection of both Golimumab 50 mg and Golimumab 100 mg.

Serious Adverse Events

	Group 1: Golimumab 50 mg	Group 2: Golimumab 100 mg	Group 3: Golimumab 50 and 100 mg
Total, serious adverse events			
# participants affected / at risk	**27/158 (17.09%)**	**26/118 (22.03%)**	**19/77 (24.68%)**
Blood and lymphatic system disorders			
Anaemia [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Cardiac disorders			
Angina Unstable [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**1/118 (0.85%)**	**0/77 (0.00%)**
Cardiac Failure [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**0/118 (0.00%)**	**1/77 (1.30%)**
Coronary Artery Disease [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**0/118 (0.00%)**	**1/77 (1.30%)**
Hypertensive Heart Disease [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**0/118 (0.00%)**	**1/77 (1.30%)**
Myocardial Infarction [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**1/77 (1.30%)**
Congenital, familial and genetic disorders			
Atrial Septal Defect [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Cryptorchism [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Gastrointestinal disorders			
Abdominal Pain [*1]			
# participants affected / at risk	**2/158 (1.27%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Abdominal Pain Upper [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Crohn's Disease [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**0/118 (0.00%)**	**1/77 (1.30%)**
Diverticulum Intestinal [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**0/118 (0.00%)**	**1/77 (1.30%)**
Duodenal Ulcer [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**

Enterocolitis [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Gastrooesophageal Reflux Disease [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	2/77 (2.60%)
Ileus [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Inguinal Hernia [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Intestinal Perforation [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Lower Gastrointestinal Haemorrhage [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Malocclusion [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Mouth Haemorrhage [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Oesophageal Stenosis [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Pancreatitis [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Small Intestinal Obstruction [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Subileus [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
General disorders			
Chest Pain [*1]			
# participants affected / at risk	0/158 (0.00%)	2/118 (1.69%)	0/77 (0.00%)
Device Occlusion [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Generalised Oedema [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Hepatobiliary disorders			
Biliary Colic [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Cholelithiasis [*1]			
# participants affected / at risk	2/158 (1.27%)	0/118 (0.00%)	0/77 (0.00%)
Hepatic Steatosis [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Hepatitis [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Hepatitis Toxic [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Infections and infestations			
Anal Abscess [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Bursitis Infective [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Cellulitis [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Cellulitis Staphylococcal [*1]			

# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Clostridial Infection [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Coccidioidomycosis [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Device Related Infection [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Diverticulitis [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Furuncle [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Herpes Zoster [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Infectious Mononucleosis [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Lyme Disease [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Otitis Media Chronic [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Pelvic Inflammatory Disease [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Pneumonia [*1]			
# participants affected / at risk	1/158 (0.63%)	1/118 (0.85%)	2/77 (2.60%)
Post Procedural Infection [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Pulmonary Tuberculosis [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Pyelonephritis [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Sepsis [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Staphylococcal Infection [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Tonsillitis [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Urosepsis [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Injury, poisoning and procedural complications			
Cervical Vertebral Fracture [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Clavicle Fracture [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Contusion [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Excoriation [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Face Injury [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Hand Fracture [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)

Humerus Fracture [*1]			
# participants affected / at risk	1/158 (0.63%)	1/118 (0.85%)	0/77 (0.00%)
Injury [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Laceration [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Ligament Rupture [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Ligament Sprain [*1]			
# participants affected / at risk	0/158 (0.00%)	2/118 (1.69%)	0/77 (0.00%)
Meniscus Lesion [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Post Procedural Haemorrhage [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Rib Fracture [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Road Traffic Accident [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Scapula Fracture [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Metabolism and nutrition disorders			
Dehydration [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Hypoglycaemia [*1]			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Musculoskeletal and connective tissue disorders			
Ankylosing Spondylitis [*1]			
# participants affected / at risk	1/158 (0.63%)	2/118 (1.69%)	1/77 (1.30%)
Arthralgia [*1]			
# participants affected / at risk	0/158 (0.00%)	2/118 (1.69%)	1/77 (1.30%)
Arthritis [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Back Pain [*1]			
# participants affected / at risk	2/158 (1.27%)	0/118 (0.00%)	1/77 (1.30%)
Intervertebral Disc Protrusion [*1]			
# participants affected / at risk	1/158 (0.63%)	1/118 (0.85%)	0/77 (0.00%)
Joint Swelling [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Knee Deformity [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Muscle Spasms [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Osteoarthritis [*1]			
# participants affected / at risk	3/158 (1.90%)	1/118 (0.85%)	3/77 (3.90%)
Prognathism [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Rotator Cuff Syndrome [*1]			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Spinal Osteoarthritis [*1]			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital Warts [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**0/118 (0.00%)**	**1/77 (1.30%)**
Basal Cell Carcinoma [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**1/118 (0.85%)**	**1/77 (1.30%)**
Lymphoma [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Pancreatic Carcinoma [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Nervous system disorders			
Cervicobrachial Syndrome [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**1/118 (0.85%)**	**0/77 (0.00%)**
Hypoaesthesia [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Migraine [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**1/118 (0.85%)**	**1/77 (1.30%)**
Multiple Sclerosis [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**1/118 (0.85%)**	**0/77 (0.00%)**
Paraesthesia [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**1/118 (0.85%)**	**0/77 (0.00%)**
Psychiatric disorders			
Alcohol Abuse [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**1/118 (0.85%)**	**0/77 (0.00%)**
Bipolar I Disorder [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Depression [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**2/118 (1.69%)**	**2/77 (2.60%)**
Hallucination [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Mania [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Mental Disorder [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**0/77 (0.00%)**
Suicidal Ideation [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**0/118 (0.00%)**	**1/77 (1.30%)**
Suicide Attempt [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**0/118 (0.00%)**	**1/77 (1.30%)**
Renal and urinary disorders			
Calculus Ureteric [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**1/118 (0.85%)**	**0/77 (0.00%)**
Nephrolithiasis [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**1/118 (0.85%)**	**0/77 (0.00%)**
Reproductive system and breast disorders			
Cystocele [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**1/118 (0.85%)**	**0/77 (0.00%)**
Endometriosis [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**0/118 (0.00%)**	**1/77 (1.30%)**
Rectocele [*1]			
# participants affected / at risk	**0/158 (0.00%)**	**1/118 (0.85%)**	**0/77 (0.00%)**

Uterine Prolapse *1			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	1/77 (1.30%)
Respiratory, thoracic and mediastinal disorders			
Asthma *1			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Dyspnoea *1			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Epistaxis *1			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Pleural Effusion *1			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	2/77 (2.60%)
Pulmonary Embolism *1			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Snoring *1			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Skin and subcutaneous tissue disorders			
Pustular Psoriasis *1			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Social circumstances			
Pregnancy of Partner *1			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Surgical and medical procedures			
Female Sterilisation *1			
# participants affected / at risk	1/158 (0.63%)	0/118 (0.00%)	0/77 (0.00%)
Vascular disorders			
Aortic Dissection *1			
# participants affected / at risk	0/158 (0.00%)	0/118 (0.00%)	1/77 (1.30%)
Haematoma *1			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)
Hypertension *1			
# participants affected / at risk	0/158 (0.00%)	1/118 (0.85%)	0/77 (0.00%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 14.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 5 years (end of study)
Additional Description	The number of participants reported at risk for adverse events (AEs) in each treatment (tx) group is based on actual tx received during the study and may differ from the number of participants who started tx in the study. Participants may be counted more than once in the analysis of AEs if they received tx at more than one dose level in the study.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Group 1: Golimumab 50 mg	Subjects who were treated with Golimumab and received Golimumab 50 mg injections only.
Group 2: Golimumab 100 mg	Subjects who were treated with Golimumab and received Golimumab 100 mg injections only.
Group 3: Golimumab 50 and 100 mg	

	Subjects who were treated with Golimumab and received at least one injection of both Golimumab 50 mg and Golimumab 100 mg.

Other Adverse Events

	Group 1: Golimumab 50 mg	Group 2: Golimumab 100 mg	Group 3: Golimumab 50 and 100 mg
Total, other (not including serious) adverse events			
# participants affected / at risk	**147/158 (93.04%)**	**113/118 (95.76%)**	**76/77 (98.70%)**
Eye disorders			
Dry Eye [*1]			
# participants affected / at risk	**1/158 (0.63%)**	**3/118 (2.54%)**	**4/77 (5.19%)**
Iritis [*1]			
# participants affected / at risk	**7/158 (4.43%)**	**7/118 (5.93%)**	**3/77 (3.90%)**
Uveitis [*1]			
# participants affected / at risk	**7/158 (4.43%)**	**10/118 (8.47%)**	**0/77 (0.00%)**
Gastrointestinal disorders			
Abdominal Discomfort [*1]			
# participants affected / at risk	**2/158 (1.27%)**	**5/118 (4.24%)**	**5/77 (6.49%)**
Abdominal Pain [*1]			
# participants affected / at risk	**8/158 (5.06%)**	**4/118 (3.39%)**	**2/77 (2.60%)**
Abdominal Pain Lower [*1]			
# participants affected / at risk	**2/158 (1.27%)**	**0/118 (0.00%)**	**4/77 (5.19%)**
Abdominal Pain Upper [*1]			
# participants affected / at risk	**12/158 (7.59%)**	**9/118 (7.63%)**	**5/77 (6.49%)**
Dental Caries [*1]			
# participants affected / at risk	**2/158 (1.27%)**	**6/118 (5.08%)**	**1/77 (1.30%)**
Diarrhoea [*1]			
# participants affected / at risk	**22/158 (13.92%)**	**16/118 (13.56%)**	**11/77 (14.29%)**
Dyspepsia [*1]			
# participants affected / at risk	**10/158 (6.33%)**	**11/118 (9.32%)**	**2/77 (2.60%)**
Gastritis [*1]			
# participants affected / at risk	**8/158 (5.06%)**	**4/118 (3.39%)**	**1/77 (1.30%)**
Nausea [*1]			
# participants affected / at risk	**16/158 (10.13%)**	**24/118 (20.34%)**	**9/77 (11.69%)**
Toothache [*1]			
# participants affected / at risk	**3/158 (1.90%)**	**7/118 (5.93%)**	**3/77 (3.90%)**
Vomiting [*1]			
# participants affected / at risk	**9/158 (5.70%)**	**8/118 (6.78%)**	**4/77 (5.19%)**
General disorders			
Chest Pain [*1]			
# participants affected / at risk	**7/158 (4.43%)**	**4/118 (3.39%)**	**5/77 (6.49%)**
Fatigue [*1]			
# participants affected / at risk	**25/158 (15.82%)**	**30/118 (25.42%)**	**10/77 (12.99%)**
Injection Site Erythema [*1]			
# participants affected / at risk	**8/158 (5.06%)**	**12/118 (10.17%)**	**10/77 (12.99%)**
Injection Site Swelling [*1]			
# participants affected / at risk	**3/158 (1.90%)**	**3/118 (2.54%)**	**5/77 (6.49%)**
Oedema Peripheral [*1]			
# participants affected / at risk	**8/158 (5.06%)**	**7/118 (5.93%)**	**4/77 (5.19%)**
Pyrexia [*1]			

# participants affected / at risk	13/158 (8.23%)	11/118 (9.32%)	4/77 (5.19%)
Hepatobiliary disorders			
Hepatic Steatosis [*1]			
# participants affected / at risk	3/158 (1.90%)	8/118 (6.78%)	2/77 (2.60%)
Immune system disorders			
Seasonal Allergy [*1]			
# participants affected / at risk	4/158 (2.53%)	4/118 (3.39%)	4/77 (5.19%)
Infections and infestations			
Bronchitis [*1]			
# participants affected / at risk	17/158 (10.76%)	12/118 (10.17%)	10/77 (12.99%)
Cellulitis [*1]			
# participants affected / at risk	7/158 (4.43%)	6/118 (5.08%)	2/77 (2.60%)
Ear Infection [*1]			
# participants affected / at risk	2/158 (1.27%)	7/118 (5.93%)	1/77 (1.30%)
Gastroenteritis [*1]			
# participants affected / at risk	9/158 (5.70%)	8/118 (6.78%)	2/77 (2.60%)
Gastroenteritis Viral [*1]			
# participants affected / at risk	1/158 (0.63%)	6/118 (5.08%)	2/77 (2.60%)
Herpes Zoster [*1]			
# participants affected / at risk	3/158 (1.90%)	4/118 (3.39%)	6/77 (7.79%)
Influenza [*1]			
# participants affected / at risk	10/158 (6.33%)	13/118 (11.02%)	10/77 (12.99%)
Lower Respiratory Tract Infection [*1]			
# participants affected / at risk	1/158 (0.63%)	4/118 (3.39%)	4/77 (5.19%)
Nasopharyngitis [*1]			
# participants affected / at risk	49/158 (31.01%)	44/118 (37.29%)	27/77 (35.06%)
Oral Herpes [*1]			
# participants affected / at risk	8/158 (5.06%)	5/118 (4.24%)	6/77 (7.79%)
Pharyngitis [*1]			
# participants affected / at risk	9/158 (5.70%)	7/118 (5.93%)	3/77 (3.90%)
Rhinitis [*1]			
# participants affected / at risk	9/158 (5.70%)	6/118 (5.08%)	4/77 (5.19%)
Sinusitis [*1]			
# participants affected / at risk	18/158 (11.39%)	19/118 (16.10%)	13/77 (16.88%)
Tooth Abscess [*1]			
# participants affected / at risk	4/158 (2.53%)	4/118 (3.39%)	4/77 (5.19%)
Tooth Infection [*1]			
# participants affected / at risk	6/158 (3.80%)	7/118 (5.93%)	0/77 (0.00%)
Upper Respiratory Tract Infection [*1]			
# participants affected / at risk	60/158 (37.97%)	42/118 (35.59%)	26/77 (33.77%)
Urinary Tract Infection [*1]			
# participants affected / at risk	6/158 (3.80%)	13/118 (11.02%)	7/77 (9.09%)
Vaginal Infection [*1]			
# participants affected / at risk	2/158 (1.27%)	0/118 (0.00%)	4/77 (5.19%)
Viral Infection [*1]			
# participants affected / at risk	1/158 (0.63%)	1/118 (0.85%)	4/77 (5.19%)
Vulvovaginal Mycotic Infection [*1]			
# participants affected / at risk	3/158 (1.90%)	7/118 (5.93%)	1/77 (1.30%)
Injury, poisoning and procedural complications			

Contusion [*1]			
# participants affected / at risk	6/158 (3.80%)	4/118 (3.39%)	6/77 (7.79%)
Laceration [*1]			
# participants affected / at risk	2/158 (1.27%)	8/118 (6.78%)	3/77 (3.90%)
Ligament Sprain [*1]			
# participants affected / at risk	9/158 (5.70%)	4/118 (3.39%)	1/77 (1.30%)
Investigations			
Alanine Aminotransferase Increased [*1]			
# participants affected / at risk	21/158 (13.29%)	20/118 (16.95%)	5/77 (6.49%)
Aspartate Aminotransferase Increased [*1]			
# participants affected / at risk	14/158 (8.86%)	12/118 (10.17%)	6/77 (7.79%)
Blood Glucose Increased [*1]			
# participants affected / at risk	2/158 (1.27%)	5/118 (4.24%)	4/77 (5.19%)
Weight Increased [*1]			
# participants affected / at risk	7/158 (4.43%)	7/118 (5.93%)	4/77 (5.19%)
Metabolism and nutrition disorders			
Hypercholesterolaemia [*1]			
# participants affected / at risk	2/158 (1.27%)	6/118 (5.08%)	1/77 (1.30%)
Musculoskeletal and connective tissue disorders			
Ankylosing Spondylitis [*1]			
# participants affected / at risk	9/158 (5.70%)	4/118 (3.39%)	5/77 (6.49%)
Arthralgia [*1]			
# participants affected / at risk	37/158 (23.42%)	28/118 (23.73%)	23/77 (29.87%)
Back Pain [*1]			
# participants affected / at risk	36/158 (22.78%)	31/118 (26.27%)	16/77 (20.78%)
Bone Pain [*1]			
# participants affected / at risk	8/158 (5.06%)	3/118 (2.54%)	1/77 (1.30%)
Bursitis [*1]			
# participants affected / at risk	5/158 (3.16%)	5/118 (4.24%)	6/77 (7.79%)
Joint Swelling [*1]			
# participants affected / at risk	8/158 (5.06%)	5/118 (4.24%)	6/77 (7.79%)
Muscle Spasms [*1]			
# participants affected / at risk	8/158 (5.06%)	5/118 (4.24%)	5/77 (6.49%)
Musculoskeletal Pain [*1]			
# participants affected / at risk	19/158 (12.03%)	9/118 (7.63%)	10/77 (12.99%)
Musculoskeletal Stiffness [*1]			
# participants affected / at risk	3/158 (1.90%)	11/118 (9.32%)	5/77 (6.49%)
Myalgia [*1]			
# participants affected / at risk	6/158 (3.80%)	10/118 (8.47%)	2/77 (2.60%)
Neck Pain [*1]			
# participants affected / at risk	16/158 (10.13%)	12/118 (10.17%)	12/77 (15.58%)
Pain in Extremity [*1]			
# participants affected / at risk	21/158 (13.29%)	14/118 (11.86%)	10/77 (12.99%)
Rotator Cuff Syndrome [*1]			
# participants affected / at risk	0/158 (0.00%)	3/118 (2.54%)	5/77 (6.49%)
Nervous system disorders			
Dizziness [*1]			
# participants affected / at risk	10/158 (6.33%)	9/118 (7.63%)	8/77 (10.39%)
Headache [*1]			

# participants affected / at risk	29/158 (18.35%)	28/118 (23.73%)	20/77 (25.97%)
Hypoaesthesia [*1]			
# participants affected / at risk	8/158 (5.06%)	6/118 (5.08%)	7/77 (9.09%)
Migraine [*1]			
# participants affected / at risk	1/158 (0.63%)	6/118 (5.08%)	5/77 (6.49%)
Paraesthesia [*1]			
# participants affected / at risk	7/158 (4.43%)	8/118 (6.78%)	3/77 (3.90%)
Psychiatric disorders			
Depression [*1]			
# participants affected / at risk	5/158 (3.16%)	7/118 (5.93%)	4/77 (5.19%)
Insomnia [*1]			
# participants affected / at risk	5/158 (3.16%)	9/118 (7.63%)	5/77 (6.49%)
Respiratory, thoracic and mediastinal disorders			
Cough [*1]			
# participants affected / at risk	30/158 (18.99%)	19/118 (16.10%)	18/77 (23.38%)
Dyspnoea [*1]			
# participants affected / at risk	7/158 (4.43%)	6/118 (5.08%)	6/77 (7.79%)
Nasal Congestion [*1]			
# participants affected / at risk	3/158 (1.90%)	5/118 (4.24%)	7/77 (9.09%)
Oropharyngeal Pain [*1]			
# participants affected / at risk	21/158 (13.29%)	12/118 (10.17%)	7/77 (9.09%)
Productive Cough [*1]			
# participants affected / at risk	14/158 (8.86%)	8/118 (6.78%)	4/77 (5.19%)
Respiratory Tract Congestion [*1]			
# participants affected / at risk	0/158 (0.00%)	2/118 (1.69%)	4/77 (5.19%)
Rhinorrhoea [*1]			
# participants affected / at risk	14/158 (8.86%)	6/118 (5.08%)	4/77 (5.19%)
Upper Respiratory Tract Congestion [*1]			
# participants affected / at risk	5/158 (3.16%)	3/118 (2.54%)	5/77 (6.49%)
Skin and subcutaneous tissue disorders			
Alopecia [*1]			
# participants affected / at risk	4/158 (2.53%)	6/118 (5.08%)	5/77 (6.49%)
Dermatitis Contact [*1]			
# participants affected / at risk	2/158 (1.27%)	1/118 (0.85%)	5/77 (6.49%)
Dry Skin [*1]			
# participants affected / at risk	1/158 (0.63%)	1/118 (0.85%)	5/77 (6.49%)
Eczema [*1]			
# participants affected / at risk	5/158 (3.16%)	5/118 (4.24%)	7/77 (9.09%)
Hyperhidrosis [*1]			
# participants affected / at risk	3/158 (1.90%)	3/118 (2.54%)	6/77 (7.79%)
Night Sweats [*1]			
# participants affected / at risk	4/158 (2.53%)	8/118 (6.78%)	4/77 (5.19%)
Pruritus [*1]			
# participants affected / at risk	11/158 (6.96%)	7/118 (5.93%)	7/77 (9.09%)
Rash [*1]			
# participants affected / at risk	17/158 (10.76%)	16/118 (13.56%)	8/77 (10.39%)
Vascular disorders			
Hypertension [*1]			
# participants affected / at risk	14/158 (8.86%)	15/118 (12.71%)	6/77 (7.79%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 14.1

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
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.

Results Point of Contact:

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Organization: Centocor Research and Development, Inc.
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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

van der Heijde D, Braun J, Deodhar A, Inman RD, Xu S, Mack ME, Hsu B. Comparison of three enthesitis indices in a multicentre, randomized, placebo-controlled trial of golimumab in ankylosing spondylitis (GO-RAISE). Rheumatology (Oxford). 2013 Feb;52(2):321-5. doi: 10.1093/rheumatology/kes251. Epub 2012 Sep 28.

van der Heijde D, Deodhar A, Inman RD, Braun J, Hsu B, Mack M. Comparison of three methods for calculating the Bath Ankylosing Spondylitis Metrology Index in a randomized placebo-controlled study. Arthritis Care Res (Hoboken). 2012 Dec;64(12):1919-22. doi: 10.1002/acr.21771.

Deodhar A, Braun J, Inman RD, Mack M, Parasuraman S, Buchanan J, Hsu B, Gathany T, van der Heijde D. Golimumab reduces sleep disturbance in patients with active ankylosing spondylitis: results from a randomized, placebo-controlled trial. Arthritis Care Res (Hoboken). 2010 Sep;62(9):1266-71. doi: 10.1002/acr.20233.

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