ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Trial record **1 of 1** for: C0524T06

Previous Study | Return to List | Next Study

An Efficacy and Safety Study of Golimumab in Patients With Active Rheumatoid Arthritis Despite Methotrexate Therapy (GO-FORWARD)

This study has been completed.

Sponsor:
Centocor, Inc.

Collaborator:
Schering-Plough

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

ClinicalTrials.gov Identifier:
NCT00264550

First received: December 11, 2005
Last updated: April 14, 2014
Last verified: April 2014
History of Changes

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

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:	Rheumatoid Arthritis
Interventions:	Drug: Golimumab 100 mg Drug: Golimumab 50 mg Drug: Methotrexate Drug: Placebo injection Drug: Placebo capsules

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 444 participants were enrolled at 60 sites in 12 countries.

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 + Methotrexate	Placebo subcutaneous (SC) injections every 4 weeks from Week 0 to Week 20 (early escape at Week 16); Methotrexate - 15 to 25mg weekly from Week 0 up to 5 yrs; Golimumab - if early escape, 50mg SC injections every 4 weeks from Week 16 up to 5 years; Golimumab - 50 mg SC injections every 4 weeks from Week 24 up to 5 yrs (unless early escape); Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 2: Golimumab 100 mg + Placebo	Golimumab 100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Placebo - 7 to 10 capsules weekly during blinded period (or Week 16 if early escape); Methotrexate - if early escape, 15 to 25mg weekly from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly

	dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 3: Golimumab 50 mg + Methotrexate	Golimumab 50 mg SC injections every 4 weeks from Week 0 up to 5 yrs (unless early escape at Week 16); Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 years; Golimumab - if early escape, 100 mg SC injections every 4 weeks from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 4: Golimumab 100 mg + Methotrexate	Golimumab100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.

Participant Flow: Overall Study

	Group 1: Placebo + Methotrexate	Group 2: Golimumab 100 mg + Placebo	Group 3: Golimumab 50 mg + Methotrexate	Group 4: Golimumab 100 mg + Methotrexate
STARTED	133	133	89	89
COMPLETED	90	92	72	59
NOT COMPLETED	43	41	17	30
Death	0	3	0	0
Lost to Follow-up	3	1	1	1
Adverse Event	23	18	9	14
Unsatisfactory therapeutic effect	4	11	4	6
Discontinued oral study agent	0	1	0	0
Not specified	13	7	3	9

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 + Methotrexate	Placebo subcutaneous (SC) injections every 4 weeks from Week 0 to Week 20 (early escape at Week 16); Methotrexate - 15 to 25mg weekly from Week 0 up to 5 yrs; Golimumab - if early escape, 50mg SC injections every 4 weeks from Week 16 up to 5 years; Golimumab - 50 mg SC injections every 4 weeks from Week 24 up to 5 yrs (unless early escape); Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 2: Golimumab 100 mg + Placebo	Golimumab 100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Placebo - 7 to 10 capsules weekly during blinded period (or Week 16 if early escape); Methotrexate - if early escape, 15 to 25mg weekly from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 3: Golimumab 50 mg + Methotrexate	Golimumab 50 mg SC injections every 4 weeks from Week 0 up to 5 yrs (unless early escape at Week 16); Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 years; Golimumab - if early escape, 100 mg SC injections every 4 weeks from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 4: Golimumab 100 mg + Methotrexate	Golimumab100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted

	after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Total	Total of all reporting groups

Baseline Measures

	Group 1: Placebo + Methotrexate	Group 2: Golimumab 100 mg + Placebo	Group 3: Golimumab 50 mg + Methotrexate	Group 4: Golimumab 100 mg + Methotrexate	Total
Number of Participants [units: participants]	**133**	**133**	**89**	**89**	**444**
Age [units: years] Mean (Standard Deviation)	**51.2 (11.96)**	**50 (11.47)**	**50.3 (10.98)**	**50 (10.78)**	**50.4 (11.36)**
Gender [units: participants]					
Female	**109**	**105**	**72**	**72**	**358**
Male	**24**	**28**	**17**	**17**	**86**

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary
Measure Title	Number of Participants Who Achieved American College of Rheumatology (ACR) 20 Response at Week 14
Measure Description	ACR 20 response is defined as a greater than or equal to 20 percent improvement from baseline in: 1. Swollen joint count (66 joints) and tender joint count (68 joints) 2. greater than or equal to 50 percentage improvement in 3 of the following 5 assessments: a. Patient's assessment of pain of pain by the Visual Analogue Scale (VAS) (0-10 cm) b.Patient's Global Assessment of Disease activity VAS (0-10 cm) c. Physician's Global Assessment of Disease Activity VAS (0-10 cm) d. Patient's assessment of physical function as measured by the Health Assessment Questionnaire (HAQ) e. 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.
All participants randomly assigned to each treatment group

Reporting Groups

	Description
Group 1: Placebo + Methotrexate	Placebo subcutaneous (SC) injections every 4 weeks from Week 0 to Week 20 (early escape at Week 16); Methotrexate - 15 to 25mg weekly from Week 0 up to 5 yrs; Golimumab - if early escape, 50mg SC injections every 4 weeks from Week 16 up to 5 years; Golimumab - 50 mg SC injections every 4 weeks from Week 24 up to 5 yrs (unless early escape); Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 2: Golimumab 100 mg + Placebo	Golimumab 100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Placebo - 7 to 10 capsules weekly during blinded period (or Week 16 if early escape); Methotrexate - if early escape, 15 to 25mg weekly from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 3: Golimumab 50 mg + Methotrexate	Golimumab 50 mg SC injections every 4 weeks from Week 0 up to 5 yrs (unless early escape at Week 16); Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 years; Golimumab - if early escape, 100 mg SC injections every 4 weeks from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding,

	dose adjusted from 50 to100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 4: Golimumab 100 mg + Methotrexate	Golimumab100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Combined Golimumab + Methotrexate	Combines Group 3 (golimumab 50 mg + methotrexate) and Group 4 (golimumab 100 mg + methotrexate)

Measured Values

	Group 1: Placebo + Methotrexate	Group 2: Golimumab 100 mg + Placebo	Group 3: Golimumab 50 mg + Methotrexate	Group 4: Golimumab 100 mg + Methotrexate	Combined Golimumab + Methotrexate
Number of Participants Analyzed [units: participants]	**133**	**133**	**89**	**89**	**178**
Number of Participants Who Achieved American College of Rheumatology (ACR) 20 Response at Week 14 [units: Participants]	**44**	**59**	**49**	**50**	**99**

Statistical Analysis 1 for Number of Participants Who Achieved American College of Rheumatology (ACR) 20 Response at Week 14

Groups [1]	Group 1: Placebo + Methotrexate vs. Combined Golimumab + Methotrexate
Method [2]	Chi-squared
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 Groups I vs III and Groups I vs IV at 0.05 level of significance. Assuming greater than 90 % power, ACR 20 response for Group I, Group III and Group IV (120, 80, and 80 participants, respectively) as 35 % for Group I and 55 % for Groups III and IV.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The positive test is defined if the comparison between combined golimumab+MTX and Group 1 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 Number of Participants Who Achieved American College of Rheumatology (ACR) 20 Response at Week 14

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 3: Golimumab 50 mg + Methotrexate
Method [2]	Chi-squared
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 Groups I vs III and Groups I vs IV at 0.05 level of significance. Samples of sizes 120, 80, 80 patients in Group I, III, and IV provide >90% power assuming 35% response in Group I and 55% ACR 20 response in golimumab groups(III & IV).
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Number of Participants Who Achieved American College of Rheumatology (ACR) 20 Response at Week 14

	Group 1: Placebo + Methotrexate vs. Group 4: Golimumab 100 mg + Methotrexate

Groups [1]	
Method [2]	Chi-squared
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 Groups I vs III and Groups I vs IV at 0.05 level of significance. Samples of sizes 120, 80, 80 patients in Group I, III, and IV provide >90% power assuming 35% response in Group I and 55% ACR 20 response in golimumab groups(III & IV).
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 4 for Number of Participants Who Achieved American College of Rheumatology (ACR) 20 Response at Week 14

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 2: Golimumab 100 mg + Placebo
Method [2]	Chi-squared
P Value [3]	0.059

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null hypothesis: No difference between Group II and Group I with respect of ACR 20 at Wk 14. Superiority of golimumab alone vs MTX alone will be demonstrated if 2-sided test is significant. Sample of 120 patients in each Group I & II provides >85% power assuming 35% ACR 20 response in Group I and 55% ACR 20 in Group II.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	This null hypothesis is tested only if a positive test for null hypothesis Statistical Analysis 1.

2. Primary: Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 24 [Time Frame: Baseline (Week 0) and Week 24]

Measure Type	Primary
Measure Title	Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 24
Measure Description	HAQ is 20-question instrument that 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 (no difficulty), to 3 (inability to perform a task in that area). The average score across the functional areas yields an overall HAQ score which ranges from 0 (no disability) to 3 (completely disabled).
Time Frame	Baseline (Week 0) and 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.
All participants randomly assigned to each treatment group

Reporting Groups

	Description
Group 1: Placebo + Methotrexate	Placebo subcutaneous (SC) injections every 4 weeks from Week 0 to Week 20 (early escape at Week 16); Methotrexate - 15 to 25mg weekly from Week 0 up to 5 yrs; Golimumab - if early escape, 50mg SC injections every 4 weeks from Week 16 up to 5 years; Golimumab - 50 mg SC injections every 4 weeks from Week 24 up to 5 yrs (unless early escape); Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after

	unblinding, dose adjusted from 50 to 100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 2: Golimumab 100 mg + Placebo	Golimumab 100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Placebo - 7 to 10 capsules weekly during blinded period (or Week 16 if early escape); Methotrexate - if early escape, 15 to 25mg weekly from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 3: Golimumab 50 mg + Methotrexate	Golimumab 50 mg SC injections every 4 weeks from Week 0 up to 5 yrs (unless early escape at Week 16); Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 years; Golimumab - if early escape, 100 mg SC injections every 4 weeks from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 4: Golimumab 100 mg + Methotrexate	Golimumab100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Combined Golimumab + Methotrexate	Combines Group 3 (golimumab 50 mg + methotrexate) and Group 4 (golimumab 100 mg + methotrexate)

Measured Values

	Group 1: Placebo + Methotrexate	Group 2: Golimumab 100 mg + Placebo	Group 3: Golimumab 50 mg + Methotrexate	Group 4: Golimumab 100 mg + Methotrexate	Combined Golimumab + Methotrexate
Number of Participants Analyzed [units: participants]	**133**	**133**	**89**	**89**	**178**
Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 24 [units: Units on a scale] Median (Inter-Quartile Range)	**0.1250 (-0.1250 to 0.3750)**	**0.1250 (-0.2500 to 0.6250)**	**0.3750 (0.1250 to 0.7500)**	**0.5000 (0.1250 to 0.7500)**	**0.4375 (0.1250 to 0.7500)**

Statistical Analysis 1 for Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Combined Golimumab + Methotrexate
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 HAQ response at Wk 24 comparing Groups I and Combined Golimumab + Methotrexate (MTX) at 0.05 level of significance.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The positive test is defined if the comparison between combined golimumab+MTX and Group I 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 Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 3: Golimumab 50 mg + Methotrexate
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 HAQ response at Wk 24 comparing Groups I and III at 0.05 level of significance.

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

Statistical Analysis 3 for Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 4: Golimumab 100 mg + Methotrexate
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 HAQ response at Wk 24 comparing Groups I and IV at 0.05 level of significance.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 4 for Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 2: Golimumab 100 mg + Placebo
Method [2]	ANOVA on van der Waerden normal scores.
P Value [3]	0.240

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null hypothesis: No difference in HAQ response at Wk 24 comparing Groups I and II at 0.05 level of significance.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

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

Measure Type	Secondary
Measure Title	Number of Participants With Disease Activity Index Score 28 (DAS 28) Using C-reactive Protein (CRP) Response at Week 14
Measure Description	DAS 28 using CRP is an index to measure the 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). Participants are considered to have a DAS 28 response if they have a score of <= 3.2 (good response) or > 3.2 to 5.1 (moderate response).
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.
All participants randomly assigned to each treatment group

Reporting Groups

	Description
Group 1: Placebo + Methotrexate	Placebo subcutaneous (SC) injections every 4 weeks from Week 0 to Week 20 (early escape at Week 16); Methotrexate - 15 to 25mg weekly from Week 0 up to 5 yrs; Golimumab - if early escape, 50mg SC injections every 4 weeks from Week 16 up to 5 years; Golimumab - 50 mg SC injections every 4 weeks from Week 24 up to 5 yrs (unless early escape); Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 2: Golimumab 100 mg + Placebo	Golimumab 100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Placebo - 7 to 10 capsules weekly during blinded period (or Week 16 if early escape); Methotrexate - if early escape, 15 to 25mg weekly from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 3: Golimumab 50 mg + Methotrexate	Golimumab 50 mg SC injections every 4 weeks from Week 0 up to 5 yrs (unless early escape at Week 16); Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 years; Golimumab - if early escape, 100 mg SC injections every 4 weeks from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 4: Golimumab 100 mg + Methotrexate	Golimumab100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Combined Golimumab + Methotrexate	Combines Group 3 (golimumab 50 mg + methotrexate) and Group 4 (golimumab 100 mg + methotrexate)

Measured Values

	Group 1: Placebo + Methotrexate	Group 2: Golimumab 100 mg + Placebo	Group 3: Golimumab 50 mg + Methotrexate	Group 4: Golimumab 100 mg + Methotrexate	Combined Golimumab + Methotrexate
Number of Participants Analyzed [units: participants]	**133**	**133**	**89**	**89**	**178**
Number of Participants With Disease Activity Index Score 28 (DAS 28) Using C-reactive Protein (CRP) Response at Week 14 [units: Participants]	**67**	**84**	**64**	**67**	**131**

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

Groups [1]	Group 1: Placebo + Methotrexate vs. Combined Golimumab + Methotrexate
Method [2]	Chi-squared
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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Number of Participants With Disease Activity Index Score 28 (DAS 28) Using C-reactive Protein (CRP) Response at Week 14

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 3: Golimumab 50 mg + Methotrexate

Method [2]	Chi-squared
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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

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

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 4: Golimumab 100 mg + Methotrexate
Method [2]	Chi-squared
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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 4 for Number of Participants With Disease Activity Index Score 28 (DAS 28) Using C-reactive Protein (CRP) Response at Week 14

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 2: Golimumab 100 mg + Placebo
Method [2]	Chi-squared
P Value [3]	0.035

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

4. Secondary: Number of Participants Who Achieved American College of Rheumatology 20 (ACR 20) Response at Week 24 [Time Frame: Week 24]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved American College of Rheumatology 20 (ACR 20) Response at Week 24
Measure Description	An ACR 20 response is defined as a greater than or equal to 20 percent improvement from baseline in: 1. Swollen joint count (66 joints) and tender joint count (68 joints) 2. greater than or equal to 50 percentage improvement in 3 of the following 5 assessments: a. Patient's assessment of pain (VAS) (0-10 cm) b.Patient's Global Assessment of Disease activity (VAS) (0-10 cm) c. Physician's Global Assessment of Disease Activity (VAS) (0-10 cm) d. Patient's assessment of physical function as measured by the Health Assessment Questionnaire (HAQ) e. C reactive protein (CRP).
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.
All participants randomly assigned to each treatment group

Reporting Groups

	Description
Group 1: Placebo + Methotrexate	Placebo subcutaneous (SC) injections every 4 weeks from Week 0 to Week 20 (early escape at Week 16); Methotrexate - 15 to 25mg weekly from Week 0 up to 5 yrs; Golimumab - if early escape, 50mg SC injections every 4 weeks from Week 16 up to 5 years; Golimumab - 50 mg SC injections every 4 weeks from Week 24 up to 5 yrs (unless early escape); Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 2: Golimumab 100 mg + Placebo	Golimumab 100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Placebo - 7 to 10 capsules weekly during blinded period (or Week 16 if early escape); Methotrexate - if early escape, 15 to 25mg weekly from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 3: Golimumab 50 mg + Methotrexate	Golimumab 50 mg SC injections every 4 weeks from Week 0 up to 5 yrs (unless early escape at Week 16); Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 years; Golimumab - if early escape, 100 mg SC injections every 4 weeks from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 4: Golimumab 100 mg + Methotrexate	Golimumab100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Combined Golimumab + Methotrexate	Combines Group 3 (golimumab 50 mg + methotrexate) and Group 4 (golimumab 100 mg + methotrexate)

Measured Values

	Group 1: Placebo + Methotrexate	**Group 2: Golimumab 100 mg + Placebo**	**Group 3: Golimumab 50 mg + Methotrexate**	**Group 4: Golimumab 100 mg + Methotrexate**	**Combined Golimumab + Methotrexate**
Number of Participants Analyzed [units: participants]	**133**	**133**	**89**	**89**	**178**
Number of Participants Who Achieved American College of Rheumatology 20 (ACR 20) Response at Week 24 [units: Participants]	**37**	**47**	**53**	**53**	**106**

Statistical Analysis 1 for Number of Participants Who Achieved American College of Rheumatology 20 (ACR 20) Response at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Combined Golimumab + Methotrexate
Method [2]	Chi-squared
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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.

Statistical Analysis 2 for Number of Participants Who Achieved American College of Rheumatology 20 (ACR 20) Response at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 3: Golimumab 50 mg + Methotrexate
Method [2]	Chi-squared
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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Number of Participants Who Achieved American College of Rheumatology 20 (ACR 20) Response at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 4: Golimumab 100 mg + Methotrexate
Method [2]	Chi-squared
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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 4 for Number of Participants Who Achieved American College of Rheumatology 20 (ACR 20) Response at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 2: Golimumab 100 mg + Placebo
Method [2]	Chi-squared
P Value [3]	0.187

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

5. Secondary: Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 14 [Time Frame: Baseline (Week 0) and Week 14]

Measure Type	Secondary
Measure Title	Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 14
Measure Description	The HAQ is 20-question instrument that 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 (no difficulty), to 3 (inability to perform a task in that area). The average score across the functional areas yields an overall HAQ score which ranges from 0 (no disability) to 3 (completely disabled).
Time Frame	Baseline (Week 0) and 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.
All participants randomly assigned to each treatment group

Reporting Groups

	Description
Group 1: Placebo + Methotrexate	Placebo subcutaneous (SC) injections every 4 weeks from Week 0 to Week 20 (early escape at Week 16); Methotrexate - 15 to 25mg weekly from Week 0 up to 5 yrs; Golimumab - if early escape, 50mg SC injections every 4 weeks from Week 16 up to 5 years; Golimumab - 50 mg SC injections every 4 weeks from Week 24 up to 5 yrs (unless early escape); Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 2: Golimumab 100 mg + Placebo	Golimumab 100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Placebo - 7 to 10 capsules weekly during blinded period (or Week 16 if early escape); Methotrexate - if early escape, 15 to 25mg weekly from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 3: Golimumab 50 mg + Methotrexate	Golimumab 50 mg SC injections every 4 weeks from Week 0 up to 5 yrs (unless early escape at Week 16); Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 years; Golimumab - if early escape, 100 mg SC injections every 4 weeks from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 4: Golimumab 100 mg + Methotrexate	Golimumab100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Combined Golimumab + Methotrexate	Combines Group 3 (golimumab 50 mg + methotrexate) and Group 4 (golimumab 100 mg + methotrexate)

Measured Values

	Group 1: Placebo + Methotrexate	**Group 2: Golimumab 100 mg + Placebo**	**Group 3: Golimumab 50 mg + Methotrexate**	**Group 4: Golimumab 100 mg + Methotrexate**	**Combined Golimumab + Methotrexate**
Number of Participants Analyzed [units: participants]	**133**	**133**	**89**	**89**	**178**
Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 14 [units: Units on a scale] Median (Inter-Quartile Range)	**0.1250 (-0.1250 to 0.3750)**	**0.2500 (-0.1250 to 0.6250)**	**0.3750 (0.1250 to 0.7500)**	**0.3750 (0.1250 to 0.6250)**	**0.3750 (0.1250 to 0.7500)**

Statistical Analysis 1 for Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 14

Groups [1]	Group 1: Placebo + Methotrexate vs. Combined Golimumab + Methotrexate
Method [2]	ANOVA on van der Waerden noramal
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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 14

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 3: Golimumab 50 mg + Methotrexate
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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 3 for Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 14

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 4: Golimumab 100 mg + Methotrexate
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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 4 for Change From Baseline in Health Assessment Questionnaire (HAQ) Score at Week 14

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 2: Golimumab 100 mg + Placebo
Method [2]	ANOVA on van der Waerden normal scores
P Value [3]	0.097

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

6. Secondary: Change From Baseline in Total Van Der Heijde Modified Sharp (vdH-S) Score at Week 24 [Time Frame: Baseline (Week 0) and Week 24]

Measure Type	Secondary

Measure Title	Change From Baseline in Total Van Der Heijde Modified Sharp (vdH-S) Score at Week 24
Measure Description	The vdH-S score is the sum of joint erosion score and joint-space narrowing (JSN) score. The total score ranges from 0 (best) to 448 (worst) with higher scores indicating more joint damage.
Time Frame	Baseline (Week 0) and 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.
All participants randomly assigned to each treatment group

Reporting Groups

	Description
Group 1: Placebo + Methotrexate	Placebo subcutaneous (SC) injections every 4 weeks from Week 0 to Week 20 (early escape at Week 16); Methotrexate - 15 to 25mg weekly from Week 0 up to 5 yrs; Golimumab - if early escape, 50mg SC injections every 4 weeks from Week 16 up to 5 years; Golimumab - 50 mg SC injections every 4 weeks from Week 24 up to 5 yrs (unless early escape); Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to 100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 2: Golimumab 100 mg + Placebo	Golimumab 100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Placebo - 7 to 10 capsules weekly during blinded period (or Week 16 if early escape); Methotrexate - if early escape, 15 to 25mg weekly from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 3: Golimumab 50 mg + Methotrexate	Golimumab 50 mg SC injections every 4 weeks from Week 0 up to 5 yrs (unless early escape at Week 16); Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 years; Golimumab - if early escape, 100 mg SC injections every 4 weeks from Week 16 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 50 to100mg and from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Group 4: Golimumab 100 mg + Methotrexate	Golimumab100 mg SC injections every 4 weeks from Week 0 up to 5 yrs; Methotrexate - 15 to 25 mg weekly from Week 0 up to 5 yrs; Methotrexate - Dr's discretion, weekly dose adjusted after unblinding; Golimumab - Dr's discretion after unblinding, dose adjusted from 100 to 50mg. Duration of the blinded period was until the week-52 database lock.
Combined Golimumab + Methotrexate	Combines Group 3 (golimumab 50 mg + methotrexate) and Group 4 (golimumab 100 mg + methotrexate)

Measured Values

	Group 1: Placebo + Methotrexate	**Group 2: Golimumab 100 mg + Placebo**	**Group 3: Golimumab 50 mg + Methotrexate**	**Group 4: Golimumab 100 mg + Methotrexate**	**Combined Golimumab + Methotrexate**
Number of Participants Analyzed [units: participants]	**133**	**133**	**89**	**89**	**178**
Change From Baseline in Total Van Der Heijde Modified Sharp (vdH-S) Score at Week 24 [units: Units on a scale] Median (Inter-Quartile Range)	**0.00 (0.00 to 0.50)**	**0.00 (0.00 to 0.50)**	**0.00 (0.00 to 0.50)**	**0.00 (0.00 to 0.50)**	**0.00 (0.00 to 0.50)**

Statistical Analysis 1 for Change From Baseline in Total Van Der Heijde Modified Sharp (vdH-S) Score at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Combined Golimumab + Methotrexate
Method [2]	ANOVA on van der Waerden normal
P Value [3]	0.551

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

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

Statistical Analysis 2 for Change From Baseline in Total Van Der Heijde Modified Sharp (vdH-S) Score at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 3: Golimumab 50 mg + Methotrexate
Method [2]	ANOVA on van der Waerden normal scores
P Value [3]	0.953

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

Statistical Analysis 3 for Change From Baseline in Total Van Der Heijde Modified Sharp (vdH-S) Score at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 4: Golimumab 100 mg + Methotrexate
Method [2]	ANOVA on van der waerden normal scores
P Value [3]	0.293

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

Statistical Analysis 4 for Change From Baseline in Total Van Der Heijde Modified Sharp (vdH-S) Score at Week 24

Groups [1]	Group 1: Placebo + Methotrexate vs. Group 2: Golimumab 100 mg + Placebo
Method [2]	ANOVA on van der Waerden normal scores
P Value [3]	0.361

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

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse event data were collected for 5 years
Additional Description	All patients randomized to the "Placebo + Methorexate" arm at baseline received golimumab at Week 16 (early escape) or Week 24 (cross over). 5-year safety data are presented according to the dose of golimumab received during the study. 10 patients did not receive any treatment with golimumab and are not included in the 5-year safety data.

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. Participants also received methotrexate capsules throughout 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. Participants also received either methotrexate or placebo capsules throughout 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. Participants also received either methotrexate or placebo capsules throughout 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	**33/105 (31.43%)**	**84/184 (45.65%)**	**55/145 (37.93%)**
Blood and lymphatic system disorders			
Anaemia † 1			
# participants affected / at risk	**0/105 (0.00%)**	**2/184 (1.09%)**	**2/145 (1.38%)**
Lymphadenopathy † 1			
# participants affected / at risk	**0/105 (0.00%)**	**0/184 (0.00%)**	**1/145 (0.69%)**
Cardiac disorders			
Acute Myocardial Infarction † 1			
# participants affected / at risk	**0/105 (0.00%)**	**2/184 (1.09%)**	**0/145 (0.00%)**
Angina Unstable † 1			
# participants affected / at risk	**0/105 (0.00%)**	**0/184 (0.00%)**	**1/145 (0.69%)**
Arteriosclerosis Coronary Artery † 1			
# participants affected / at risk	**0/105 (0.00%)**	**1/184 (0.54%)**	**0/145 (0.00%)**
Atrial Fibrillation † 1			
# participants affected / at risk	**1/105 (0.95%)**	**1/184 (0.54%)**	**0/145 (0.00%)**
Atrioventricular Block † 1			
# participants affected / at risk	**0/105 (0.00%)**	**0/184 (0.00%)**	**1/145 (0.69%)**
Cardiac Failure † 1			
# participants affected / at risk	**0/105 (0.00%)**	**0/184 (0.00%)**	**1/145 (0.69%)**
Cardiovascular Insufficiency † 1			
# participants affected / at risk	**0/105 (0.00%)**	**1/184 (0.54%)**	**0/145 (0.00%)**
Congestive Cardiomyopathy † 1			
# participants affected / at risk	**0/105 (0.00%)**	**1/184 (0.54%)**	**0/145 (0.00%)**
Coronary Artery Disease † 1			
# participants affected / at risk	**0/105 (0.00%)**	**1/184 (0.54%)**	**0/145 (0.00%)**
Cyanosis † 1			
# participants affected / at risk	**1/105 (0.95%)**	**0/184 (0.00%)**	**0/145 (0.00%)**
Dressler's Syndrome † 1			
# participants affected / at risk	**0/105 (0.00%)**	**1/184 (0.54%)**	**0/145 (0.00%)**
Myocardial Infarction † 1			
# participants affected / at risk	**0/105 (0.00%)**	**0/184 (0.00%)**	**1/145 (0.69%)**

Myocardial Ischaemia [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Supraventricular Tachycardia [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Ear and labyrinth disorders			
Deafness Neurosensory [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Endocrine disorders			
Goitre [†1]			
# participants affected / at risk	2/105 (1.90%)	0/184 (0.00%)	2/145 (1.38%)
Eye disorders			
Retinal Detachment [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Scleritis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Scotoma [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Gastrointestinal disorders			
Abdominal Pain [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	2/145 (1.38%)
Abdominal Pain Upper [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Colitis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Diarrhoea [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Diverticulum Intestinal [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Duodenal Ulcer [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Gastric Ulcer [†1]			
# participants affected / at risk	1/105 (0.95%)	1/184 (0.54%)	0/145 (0.00%)
Gastrointestinal Haemorrhage [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Gastrooesophageal Reflux Disease [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Inguinal Hernia [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Oesophagitis Ulcerative [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Pancreatitis [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Pancreatitis Acute [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Parotid Gland Enlargement [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Small Intestinal Obstruction [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
General disorders			

Chest Pain [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	1/145 (0.69%)
Necrosis [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Pain [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Pyrexia [†1]			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	0/145 (0.00%)
Hepatobiliary disorders			
Acute Hepatic Failure [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Biliary Colic [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	2/145 (1.38%)
Cholecystitis [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	2/145 (1.38%)
Cholelithiasis [†1]			
# participants affected / at risk	0/105 (0.00%)	5/184 (2.72%)	3/145 (2.07%)
Hepatitis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Immune system disorders			
Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Sarcoidosis [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Infections and infestations			
Abscess Limb [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Arthritis Bacterial [†1]			
# participants affected / at risk	1/105 (0.95%)	2/184 (1.09%)	0/145 (0.00%)
Arthritis Infective [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Bronchitis [†1]			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	1/145 (0.69%)
Cellulitis [†1]			
# participants affected / at risk	1/105 (0.95%)	4/184 (2.17%)	1/145 (0.69%)
Chronic Sinusitis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Chronic Tonsillitis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Disseminated Tuberculosis [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Diverticulitis [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Empyema [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Gastroenteritis [†1]			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	1/145 (0.69%)
Hepatitis E [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)

Herpes Zoster [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Incision Site Cellulitis [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Lobar Pneumonia [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Lower Respiratory Tract Infection [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Mastoiditis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Osteomyelitis [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Otitis Externa [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Peritoneal Tuberculosis [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Pneumonia [†1]			
# participants affected / at risk	2/105 (1.90%)	3/184 (1.63%)	2/145 (1.38%)
Pneumonia Primary Atypical [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Postoperative Wound Infection [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Pulmonary Tuberculosis [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Pyelonephritis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	1/145 (0.69%)
Pyelonephritis Acute [†1]			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	0/145 (0.00%)
Sepsis [†1]			
# participants affected / at risk	1/105 (0.95%)	5/184 (2.72%)	1/145 (0.69%)
Septic Arthritis Staphylococcal [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Septic Shock [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Sinusitis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Subcutaneous Abscess [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Tuberculous Pleurisy [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Upper Respiratory Tract Infection [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Urinary Tract Infection [†1]			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	0/145 (0.00%)
Vulval Cellulitis [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Injury, poisoning and procedural complications			
Abdominal Injury [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)

Ankle Fracture [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Brain Contusion [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Clavicle Fracture [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Contusion [†1]			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	0/145 (0.00%)
Craniocerebral Injury [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Femoral Neck Fracture [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Femur Fracture [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Foot Fracture [†1]			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	0/145 (0.00%)
Hand Fracture [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Laceration [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	1/145 (0.69%)
Ligament Sprain [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Limb Crushing Injury [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Limb Injury [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Lumbar Vertebral Fracture [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Postpericardiotomy Syndrome [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Spinal Column Injury [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Tendon Injury [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Tendon Rupture [†1]			
# participants affected / at risk	1/105 (0.95%)	1/184 (0.54%)	0/145 (0.00%)
Tibia Fracture [†1]			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	0/145 (0.00%)
Upper Limb Fracture [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Wrist Fracture [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	1/145 (0.69%)
Investigations			
Weight Decreased [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Metabolism and nutrition disorders			
Decreased Appetite [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Musculoskeletal and connective tissue disorders			

Arthralgia [†1]			
# participants affected / at risk	1/105 (0.95%)	3/184 (1.63%)	2/145 (1.38%)
Arthritis [†1]			
# participants affected / at risk	1/105 (0.95%)	2/184 (1.09%)	0/145 (0.00%)
Arthropathy [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Bone Pain [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Bunion [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	1/145 (0.69%)
Chondropathy [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Foot Deformity [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	1/145 (0.69%)
Intervertebral Disc Protrusion [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	2/145 (1.38%)
Joint Destruction [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	2/145 (1.38%)
Lumbar Spinal Stenosis [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Osteoarthritis [†1]			
# participants affected / at risk	1/105 (0.95%)	3/184 (1.63%)	3/145 (2.07%)
Rheumatoid Arthritis [†1]			
# participants affected / at risk	2/105 (1.90%)	6/184 (3.26%)	5/145 (3.45%)
Rheumatoid Nodule [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Scoliosis [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Soft Tissue Necrosis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Spinal Column Stenosis [†1]			
# participants affected / at risk	1/105 (0.95%)	1/184 (0.54%)	0/145 (0.00%)
Spondylolisthesis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Synovitis [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma [†1]			
# participants affected / at risk	2/105 (1.90%)	4/184 (2.17%)	1/145 (0.69%)
Bowen's Disease [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Breast Cancer [†1]			
# participants affected / at risk	1/105 (0.95%)	2/184 (1.09%)	0/145 (0.00%)
Breast Cancer in Situ [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Bronchial Carcinoma [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Endometrial Cancer [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)

Gastric Cancer [†1]			
# participants affected / at risk	1/105 (0.95%)	1/184 (0.54%)	0/145 (0.00%)
Haemangioma [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Lung Adenocarcinoma Metastatic [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Lung Neoplasm Malignant [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Lymphoma [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Lymphoproliferative Disorder [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Malignant Melanoma [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Neuroma [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Prostate Cancer [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Squamous Cell Carcinoma [†1]			
# participants affected / at risk	2/105 (1.90%)	2/184 (1.09%)	2/145 (1.38%)
Thyroid Adenoma [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Thyroid Cancer [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Uterine Leiomyoma [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	3/145 (2.07%)
Nervous system disorders			
Axonal Neuropathy [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Carotid Artery Stenosis [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Cerebrovascular Accident [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Convulsion [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Hypoaesthesia [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Lumbar Radiculopathy [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	1/145 (0.69%)
Migraine [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Paresis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Syncope [†1]			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	1/145 (0.69%)
Psychiatric disorders			
Suicide Attempt [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Renal and urinary disorders			
Calculus Urinary [†1]			

# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Incontinence [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Nephrolithiasis [†1]			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	1/145 (0.69%)
Nephrotic Syndrome [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Renal Failure [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Stress Urinary Incontinence [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Reproductive system and breast disorders			
Breast Calcifications [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Breast Enlargement [†1]			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Cystocele [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Dysfunctional Uterine Bleeding [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Endometriosis [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Menopausal Symptoms [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Menorrhagia [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Pelvic Adhesions [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Uterine Prolapse [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	1/145 (0.69%)
Respiratory, thoracic and mediastinal disorders			
Acute Pulmonary Oedema [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Asthma [†1]			
# participants affected / at risk	1/105 (0.95%)	1/184 (0.54%)	0/145 (0.00%)
Atelectasis [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Chronic Obstructive Pulmonary Disease [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Haemothorax [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Interstitial Lung Disease [†1]			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Lung Disorder [†1]			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	0/145 (0.00%)
Nasal Septum Disorder [†1]			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Obstructive Airways Disorder [†1]			

# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Pleurisy † 1			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Pneumonitis † 1			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Pulmonary Embolism † 1			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	0/145 (0.00%)
Respiratory Distress † 1			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Vocal Cord Disorder † 1			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Vocal Cord Polyp † 1			
# participants affected / at risk	1/105 (0.95%)	0/184 (0.00%)	0/145 (0.00%)
Skin and subcutaneous tissue disorders			
Decubitus Ulcer † 1			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Drug Eruption † 1			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)
Psoriasis † 1			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Vascular disorders			
Deep Vein Thrombosis † 1			
# participants affected / at risk	0/105 (0.00%)	2/184 (1.09%)	0/145 (0.00%)
Hypertensive Emergency † 1			
# participants affected / at risk	0/105 (0.00%)	1/184 (0.54%)	0/145 (0.00%)
Venous Thrombosis † 1			
# participants affected / at risk	0/105 (0.00%)	0/184 (0.00%)	1/145 (0.69%)

† 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	All patients randomized to the "Placebo + Methorexate" arm at baseline received golimumab at Week 16 (early escape) or Week 24 (cross over). 5-year safety data are presented according to the dose of golimumab received during the study. 10 patients did not receive any treatment with golimumab and are not included in the 5-year safety data.

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. Participants also received methotrexate capsules throughout 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. Participants also received either methotrexate or placebo capsules throughout 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. Participants also received either methotrexate or placebo capsules throughout 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	96/105 (91.43%)	160/184 (86.96%)	118/145 (81.38%)
Blood and lymphatic system disorders			
Anaemia † 1			
# participants affected / at risk	5/105 (4.76%)	11/184 (5.98%)	7/145 (4.83%)
Gastrointestinal disorders			
Abdominal Pain † 1			
# participants affected / at risk	3/105 (2.86%)	11/184 (5.98%)	7/145 (4.83%)
Abdominal Pain Upper † 1			
# participants affected / at risk	9/105 (8.57%)	13/184 (7.07%)	15/145 (10.34%)
Diarrhoea † 1			
# participants affected / at risk	16/105 (15.24%)	24/184 (13.04%)	11/145 (7.59%)
Dyspepsia † 1			
# participants affected / at risk	7/105 (6.67%)	11/184 (5.98%)	4/145 (2.76%)
Gastritis † 1			
# participants affected / at risk	7/105 (6.67%)	9/184 (4.89%)	5/145 (3.45%)
Gastrooesophageal Reflux Disease † 1			
# participants affected / at risk	5/105 (4.76%)	6/184 (3.26%)	8/145 (5.52%)
Nausea † 1			
# participants affected / at risk	9/105 (8.57%)	23/184 (12.50%)	11/145 (7.59%)
General disorders			
Fatigue † 1			
# participants affected / at risk	11/105 (10.48%)	9/184 (4.89%)	3/145 (2.07%)
Injection Site Erythema † 1			
# participants affected / at risk	4/105 (3.81%)	20/184 (10.87%)	3/145 (2.07%)
Oedema Peripheral † 1			
# participants affected / at risk	2/105 (1.90%)	10/184 (5.43%)	9/145 (6.21%)
Infections and infestations			
Bronchitis † 1			
# participants affected / at risk	18/105 (17.14%)	27/184 (14.67%)	28/145 (19.31%)
Fungal Skin Infection † 1			
# participants affected / at risk	6/105 (5.71%)	2/184 (1.09%)	2/145 (1.38%)
Gastroenteritis † 1			
# participants affected / at risk	4/105 (3.81%)	11/184 (5.98%)	7/145 (4.83%)
Herpes Zoster † 1			

# participants affected / at risk	9/105 (8.57%)	11/184 (5.98%)	10/145 (6.90%)
Influenza [†1]			
# participants affected / at risk	4/105 (3.81%)	11/184 (5.98%)	9/145 (6.21%)
Nasopharyngitis [†1]			
# participants affected / at risk	15/105 (14.29%)	35/184 (19.02%)	24/145 (16.55%)
Oral Herpes [†1]			
# participants affected / at risk	4/105 (3.81%)	9/184 (4.89%)	11/145 (7.59%)
Pharyngitis [†1]			
# participants affected / at risk	13/105 (12.38%)	20/184 (10.87%)	25/145 (17.24%)
Rhinitis [†1]			
# participants affected / at risk	7/105 (6.67%)	5/184 (2.72%)	3/145 (2.07%)
Sinusitis [†1]			
# participants affected / at risk	6/105 (5.71%)	20/184 (10.87%)	16/145 (11.03%)
Upper Respiratory Tract Infection [†1]			
# participants affected / at risk	39/105 (37.14%)	64/184 (34.78%)	39/145 (26.90%)
Urinary Tract Infection [†1]			
# participants affected / at risk	9/105 (8.57%)	20/184 (10.87%)	20/145 (13.79%)
Injury, poisoning and procedural complications			
Contusion [†1]			
# participants affected / at risk	5/105 (4.76%)	13/184 (7.07%)	8/145 (5.52%)
Investigations			
Alanine Aminotransferase Increased [†1]			
# participants affected / at risk	8/105 (7.62%)	19/184 (10.33%)	11/145 (7.59%)
Aspartate Aminotransferase Increased [†1]			
# participants affected / at risk	5/105 (4.76%)	17/184 (9.24%)	7/145 (4.83%)
Metabolism and nutrition disorders			
Hypercholesterolaemia [†1]			
# participants affected / at risk	7/105 (6.67%)	14/184 (7.61%)	10/145 (6.90%)
Musculoskeletal and connective tissue disorders			
Arthralgia [†1]			
# participants affected / at risk	16/105 (15.24%)	18/184 (9.78%)	15/145 (10.34%)
Back Pain [†1]			
# participants affected / at risk	10/105 (9.52%)	22/184 (11.96%)	20/145 (13.79%)
Musculoskeletal Pain [†1]			
# participants affected / at risk	4/105 (3.81%)	10/184 (5.43%)	7/145 (4.83%)
Osteoporosis [†1]			

# participants affected / at risk	4/105 (3.81%)	10/184 (5.43%)	4/145 (2.76%)
Pain in Extremity † 1			
# participants affected / at risk	4/105 (3.81%)	10/184 (5.43%)	6/145 (4.14%)
Rheumatoid Arthritis † 1			
# participants affected / at risk	13/105 (12.38%)	22/184 (11.96%)	15/145 (10.34%)
Nervous system disorders			
Headache † 1			
# participants affected / at risk	13/105 (12.38%)	22/184 (11.96%)	20/145 (13.79%)
Psychiatric disorders			
Depression † 1			
# participants affected / at risk	1/105 (0.95%)	10/184 (5.43%)	10/145 (6.90%)
Insomnia † 1			
# participants affected / at risk	3/105 (2.86%)	11/184 (5.98%)	9/145 (6.21%)
Respiratory, thoracic and mediastinal disorders			
Cough † 1			
# participants affected / at risk	24/105 (22.86%)	35/184 (19.02%)	14/145 (9.66%)
Oropharyngeal Pain † 1			
# participants affected / at risk	10/105 (9.52%)	10/184 (5.43%)	7/145 (4.83%)
Productive Cough † 1			
# participants affected / at risk	8/105 (7.62%)	8/184 (4.35%)	1/145 (0.69%)
Rhinorrhoea † 1			
# participants affected / at risk	7/105 (6.67%)	6/184 (3.26%)	6/145 (4.14%)
Upper Respiratory Tract Congestion † 1			
# participants affected / at risk	7/105 (6.67%)	3/184 (1.63%)	3/145 (2.07%)
Skin and subcutaneous tissue disorders			
Pruritus † 1			
# participants affected / at risk	6/105 (5.71%)	6/184 (3.26%)	4/145 (2.76%)
Rash † 1			
# participants affected / at risk	3/105 (2.86%)	19/184 (10.33%)	15/145 (10.34%)
Skin Lesion † 1			
# participants affected / at risk	8/105 (7.62%)	6/184 (3.26%)	2/145 (1.38%)
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	8/105 (7.62%)	25/184 (13.59%)	21/145 (14.48%)

† 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.

Results Point of Contact:

Name/Title: Director Clinical Research
Organization: Centocor Research & Development, Inc.
phone: 1-800-457-6399

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

Baker JF, Conaghan PG, Smolen JS, Aletaha D, Shults J, Emery P, Baker DG, Ostergaard M. Development and validation of modified disease activity scores in rheumatoid arthritis: superior correlation with magnetic resonance imaging-detected synovitis and radiographic progression. Arthritis Rheumatol. 2014 Apr;66(4):794-802. doi: 10.1002/art.38304.

Keystone EC, Genovese MC, Hall S, Miranda PC, Bae SC, Palmer W, Wu Z, Xu S, Hsia EC. Golimumab in patients with active rheumatoid arthritis despite methotrexate therapy: results through 2 years of the GO-FORWARD study extension. J Rheumatol. 2013 Jul;40(7):1097-103. doi: 10.3899/jrheum.120584. Epub 2013 May 15.

Visvanathan S, Rahman MU, Keystone E, Genovese M, Klareskog L, Hsia E, Mack M, Buchanan J, Elashoff M, Wagner C. Association of serum markers with improvement in clinical response measures after treatment with golimumab in patients with active rheumatoid arthritis despite receiving methotrexate: results from the GO-FORWARD study. Arthritis Res Ther. 2010;12(6):R211. doi: 10.1186/ar3188. Epub 2010 Nov 17.

Responsible Party:	Centocor, Inc.
ClinicalTrials.gov Identifier:	NCT00264550 History of Changes
Other Study ID Numbers:	CR006343 **C0524T06** (Other Identifier: Centocor) 2004-003296-36 (EudraCT Number)
Study First Received:	December 11, 2005
Results First Received:	May 21, 2009
Last Updated:	April 14, 2014
Health Authority:	United States: Food and Drug Administration

Disclaimer

Information in this posting shall not be considered to be a claim for any marketed product. Some information in this posting may differ from the approved labeling for the product. Please refer to the full prescribing information for indications and proper use of the product.