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Trial record **1 of 1** for: C0524T03

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A Study of Safety and Efficacy of CNTO 148 in Patients With Severe Persistent Asthma

This study has been completed.

Sponsor:
Centocor, Inc.

Collaborator:
Centocor BV

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

ClinicalTrials.gov Identifier:
NCT00207740

First received: September 13, 2005
Last updated: August 14, 2012
Last verified: August 2012
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, Investigator); Primary Purpose: Treatment
Condition:	Asthma
Interventions:	Drug: CNTO148 Drug: 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
A total of 309 patients were randomized into 4 parallel treatment groups at 53 sites (134 patients at 27 sites in the US and 175 patients at 26 sites in Europe). The first patient was consented on 31 Aug 2004, and the last patient completed the study on 17 Jul 2007.

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 I: Placebo	Placebo subcutaneous (SC) injections every 4 weeks (Wks) from week (Wk) 0 to Wk 52
Group II: Golimumab 50 mg	Golimumab (CNTO148) 75 mg SC injection at Wk 0 followed by 50 mg SC injections every 4 Wks to Wk 52
Group III: Golimumab 100 mg	Golimumab 150 mg SC injection at Wk 0 followed by 100 mg SC injections every 4 Wks to Wk 52
Group IV: Golimumab 200 mg	Golimumab 300 mg SC injection at Wk 0 followed by 200 mg SC injections every 4 Wks to Wk 52

Participant Flow: Overall Study

	Group I: Placebo	**Group II: Golimumab 50 mg**	**Group III: Golimumab 100 mg**	**Group IV: Golimumab 200 mg**
STARTED	**78**	**77**	**76**	**78**
COMPLETED	**49** [1]	**36** [1]	**36** [1]	**35** [1]
NOT COMPLETED	**29**	**41**	**40**	**43**

Adverse Event	**4**	**14**	**14**	**11**
Unsatisfactory therapeutic effect	**1**	**0**	**2**	**4**
Lost to Follow-up	**0**	**2**	**1**	**1**
Death	**0**	**0**	**0**	**1**
Sponsor Directive	**22**	**15**	**16**	**21**
Not Specified	**2**	**10**	**7**	**5**

[1] Indicates number of patients who received subcutaneous study medication through Week 52

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 subcutaneous (SC) injections every 4 weeks (Wks) from week (Wk) 0 to Wk 52
Group II: Golimumab 50 mg	Golimumab (CNTO148) 75 mg SC injection at Wk 0 followed by 50 mg SC injections every 4 Wks to Wk 52
Group III: Golimumab 100 mg	Golimumab 150 mg SC injection at Wk 0 followed by 100 mg SC injections every 4 Wks to Wk 52
Group IV: Golimumab 200 mg	Golimumab 300 mg SC injection at Wk 0 followed by 200 mg SC injections every 4 Wks to Wk 52
Total	Total of all reporting groups

Baseline Measures

	Group I: Placebo	**Group II: Golimumab 50 mg**	**Group III: Golimumab 100 mg**	**Group IV: Golimumab 200 mg**	**Total**
Number of Participants [units: participants]	**78**	**77**	**76**	**78**	**309**
Age [units: years] Mean (Standard Deviation)	**49.4 (12.03)**	**49.4 (11.26)**	**49.1 (12.85)**	**52.7 (12.26)**	**50.1 (12.14)**
Gender [units: participants]					
Female	**42**	**46**	**39**	**46**	**173**
Male	**36**	**31**	**37**	**32**	**136**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Prebronchodilator Clinic-Measured, Percent-Predicted Forced Expiratory Volume in 1 Second [Time Frame: Baseline and Week 24]

Measure Type	Primary
Measure Title	Change From Baseline in Prebronchodilator Clinic-Measured, Percent-Predicted Forced Expiratory Volume in 1 Second
Measure Description	The endpoint is change from baseline in prebronchodilator clinic-measured percent predicted Percent-Predicted Forced Expiratory Volume in 1 Second (FEV1) with Last Observation Carried Forward (LOCF) at 6 months. The baseline visit starts at the end of 2 weeks run in phase.
Time Frame	Baseline 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.
The analysis of this endpoint uses intent-to-treat population. Missing data were imputed using Last Observation Carried Forward (LOCF).

Reporting Groups

	Description
Group I: Placebo	Placebo subcutaneous (SC) injections every 4 weeks (Wks) from week (Wk) 0 to Wk 52
Group II: Golimumab 50 mg	Golimumab (CNTO148) 75 milligram (mg) SC injection at Wk 0 followed by 50 mg SC injections every 4 Wks to Wk 52
Group III: Golimumab 100 mg	Golimumab 150 mg SC injection at Wk 0 followed by 100 mg SC injections every 4 Wks to Wk 52
Group IV: Golimumab 200 mg	Golimumab 300 mg SC injection at Wk 0 followed by 200 mg SC injections every 4 Wks to Wk 52
Combined: Group III & IV	Combines Group III (golimumab 100 mg) and Group IV (golimumab 200 mg)

Measured Values

	Group I: Placebo	Group II: Golimumab 50 mg	Group III: Golimumab 100 mg	Group IV: Golimumab 200 mg	Combined: Group III & IV
Number of Participants Analyzed [units: participants]	**78**	**77**	**76**	**78**	**154**
Change From Baseline in Prebronchodilator Clinic-Measured, Percent-Predicted Forced Expiratory Volume in 1 Second [units: Percent predicted] Least Squares Mean (95% Confidence Interval)	**2.44 (-0.574 to 5.461)**	**0.48 (-2.563 to 3.519)**	**3.22 (0.149 to 6.295)**	**2.59 (-0.441 to 5.620)**	**2.91 (0.696 to 5.116)**

Statistical Analysis 1 for Change From Baseline in Prebronchodilator Clinic-Measured, Percent-Predicted Forced Expiratory Volume in 1 Second

Groups [1]	Group I: Placebo vs. Combined: Group III & IV
Method [2]	ANCOVA
P Value [3]	0.802

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis was that the endpoint for placebo is the same as that for combined 100 mg and 200 mg golimumab. Assuming a standard deviation of 23%, there is 86% power to detect a 10% difference at a 0.05 significance level.
[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:
	When interpreting this p-value along with the other co-primary endpoint, Hochberg procedure was used.

Statistical Analysis 2 for Change From Baseline in Prebronchodilator Clinic-Measured, Percent-Predicted Forced Expiratory Volume in 1 Second

Groups [1]	Group I: Placebo vs. Group IV: Golimumab 200 mg
Method [2]	ANCOVA
P Value [3]	0.945

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	This is a secondary analysis.
[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 nominal p-value is for descriptive purpose only.

Statistical Analysis 3 for Change From Baseline in Prebronchodilator Clinic-Measured, Percent-Predicted Forced Expiratory Volume in 1 Second

Groups [1]	Group I: Placebo vs. Group III: Golimumab 100 mg
Method [2]	ANCOVA
P Value [3]	0.717

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	This is a secondary analysis.
[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 nominal p-value is for descriptive purpose only.

Statistical Analysis 4 for Change From Baseline in Prebronchodilator Clinic-Measured, Percent-Predicted Forced Expiratory Volume in 1 Second

Groups [1]	Group I: Placebo vs. Group II: Golimumab 50 mg
Method [2]	ANCOVA
P Value [3]	0.357

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	This is a secondary analysis.
[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 nominal p-value is for descriptive purpose only.

2. Primary: Number of Severe Asthma Exacerbations Per Patient From Baseline Through 6 Months [Time Frame: Baseline to Week 24]

Measure Type	Primary
Measure Title	Number of Severe Asthma Exacerbations Per Patient From Baseline Through 6 Months
Measure Description	The endpoint is the average number of severe asthma exacerbations per patient from baseline through 6 months.
Time Frame	Baseline to Week 24
Safety Issue	Yes

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.
The analysis of this endpoint uses intent-to-treat population. For the dropouts, the worst case in similar patients was used as the number of severe exacerbations.

Reporting Groups

	Description
Group I: Placebo	Placebo subcutaneous (SC) injections every 4 weeks (Wks) from week (Wk) 0 to Wk 52
Group II: Golimumab 50 mg	Golimumab 75 milligram (mg) SC injection at Wk 0 followed by 50 mg SC injections every 4 Wks to Wk 52
Group III: Golimumab 100 mg	Golimumab 150 mg SC injection at Wk 0 followed by 100 mg SC injections every 4 Wks to Wk 52

Group IV: Golimumab 200 mg	Golimumab 300 mg SC injection at Wk 0 followed by 200 mg SC injections every 4 Wks to Wk 52
Combined: Group III & IV	Combines Group III (golimumab 100 mg) and Group IV (golimumab 200 mg)

Measured Values

	Group I: Placebo	Group II: Golimumab 50 mg	Group III: Golimumab 100 mg	Group IV: Golimumab 200 mg	Combined: Group III & IV
Number of Participants Analyzed [units: participants]	**78**	**77**	**76**	**78**	**154**
Number of Severe Asthma Exacerbations Per Patient From Baseline Through 6 Months [units: Events per patient through week (Wk) 24] Mean (Standard Deviation)	**0.5 (1.07)**	**0.7 (1.18)**	**0.4 (0.85)**	**0.5 (1.08)**	**0.5 (0.97)**

Statistical Analysis 1 for Number of Severe Asthma Exacerbations Per Patient From Baseline Through 6 Months

Groups [1]	Group I: Placebo vs. Combined: Group III & IV
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.718

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis was that the number of severe exacerbations per patient from baseline through week 24 for placebo is the same as that in the combined 100 mg and 200 mg golimumab. Assuming 1 severe exacerbation over 6 months per patient in the placebo group, there is 79% power to detect a 35% reduction in the combined 100 mg and 200 mg golimumab group at a 0.05 significance level.
[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:
	When interpreting this p-value along with the other co-primary endpoint, Hochberg procedure was used.

Statistical Analysis 2 for Number of Severe Asthma Exacerbations Per Patient From Baseline Through 6 Months

Groups [1]	Group I: Placebo vs. Group IV: Golimumab 200 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.779

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	This is a secondary analysis.
[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 nominal p-value is for descriptive purpose only.

Statistical Analysis 3 for Number of Severe Asthma Exacerbations Per Patient From Baseline Through 6 Months

Groups [1]	Group I: Placebo vs. Group III: Golimumab 100 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.649

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	This is a secondary analysis.
[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 nominal p-value is for descriptive purpose only.

Statistical Analysis 4 for Number of Severe Asthma Exacerbations Per Patient From Baseline Through 6 Months

Groups [1]	Group I: Placebo vs. Group II: Golimumab 50 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.256

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	This is a secondary analysis.
[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 nominal p-value is for descriptive purpose only.

3. Secondary: Change From Baseline in Asthma Quality of Life Questionnaire Score at 6 Months; Randomized Patients [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Asthma Quality of Life Questionnaire Score at 6 Months; Randomized Patients
Measure Description	The endpoint is the change from baseline in the overall Asthma Quality of Life Questionnaire (AQLQ) score at 6 months. The AQLQ is a validated and self-administered questionnaire to evaluate symptoms and Quality of Life (QOL) in subjects with asthma and it has 32 questions in 4 domains (symptoms, activity limitations, emotional function, and environmental stimuli). Participants were asked to score the importance of each of the positively identified problems on a 7-point scale (7 = not impaired at all - 1 = severely impaired).
Time Frame	Baseline to Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis of this endpoint uses intent-to-treat population. Missing data were imputed using last observation carried forward.

Reporting Groups

	Description
Group I: Placebo	Placebo subcutaneous (SC) injections every 4 weeks (Wks) from week (Wk) 0 to Wk 52
Group II: Golimumab 50 mg	Golimumab (CNTO148) 75 milligram (mg) SC injection at Wk 0 followed by 50 mg SC injections every 4 Wks to Wk 52
Group III: Golimumab 100 mg	Golimumab 150 mg SC injection at Wk 0 followed by 100 mg SC injections every 4 Wks to Wk 52
Group IV: Golimumab 200 mg	Golimumab 300 mg SC injection at Wk 0 followed by 200 mg SC injections every 4 Wks to Wk 52
Combined: Group III & IV	Combines Group III (golimumab 100 mg) and Group IV (golimumab 200 mg)

Measured Values

	Group I: Placebo	**Group II: Golimumab 50 mg**	**Group III: Golimumab 100 mg**	**Group IV: Golimumab 200 mg**	**Combined: Group III & IV**
Number of Participants Analyzed [units: participants]	**78**	**77**	**76**	**78**	**154**

Change From Baseline in Asthma Quality of Life Questionnaire Score at 6 Months; Randomized Patients [units: Points on scale] Median (Inter-Quartile Range)	**0.42 (0.00 to 1.13)**	**0.53 (0.00 to 1.13)**	**0.86 (-0.02 to 1.47)**	**0.55 (0.00 to 1.00)**	**0.66 (0.00 to 1.34)**

Statistical Analysis 1 for Change From Baseline in Asthma Quality of Life Questionnaire Score at 6 Months; Randomized Patients

Groups [1]	Group I: Placebo vs. Combined: Group III & IV
Method [2]	Wilcoxon (Mann-Whitney)
P Value [3]	0.286

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis was that the endpoint for placebo is the same as that in the combined 100 mg and 200 mg golimumab.
[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 Asthma Quality of Life Questionnaire Score at 6 Months; Randomized Patients

Groups [1]	Group I: Placebo vs. Group IV: Golimumab 200 mg
Method [2]	Wilcoxon (Mann-Whitney)
P Value [3]	0.742

[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 Asthma Quality of Life Questionnaire Score at 6 Months; Randomized Patients

Groups [1]	Group I: Placebo vs. Group III: Golimumab 100 mg
Method [2]	Wilcoxon (Mann-Whitney)
P Value [3]	0.128

[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 Asthma Quality of Life Questionnaire Score at 6 Months; Randomized Patients

Groups [1]	Group I: Placebo vs. Group II: Golimumab 50 mg
Method [2]	Wilcoxon (Mann-Whitney)
P Value [3]	0.946

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

4. Secondary: Change From Baseline in Rescue Medication Use at 6 Months; Randomized Patients [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Rescue Medication Use at 6 Months; Randomized Patients
Measure Description	The endpoint is change from baseline in rescue medication use at Wk 24 where the rescue medication use was based on the average over 7 days prior to visit.
Time Frame	Baseline to Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis of this endpoint uses intent-to-treat population. Missing data were imputed using last observation carried forward.

Reporting Groups

	Description
Group I: Placebo	Placebo subcutaneous (SC) injections every 4 weeks (Wks) from week (Wk) 0 to Wk 52
Group II: Golimumab 50 mg	Golimumab 75 mg SC injection at Wk 0 followed by 50 mg SC injections every 4 Wks to Wk 52
Group III: Golimumab 100 mg	Golimumab 150 mg SC injection at Wk 0 followed by 100 mg SC injections every 4 Wks to Wk 52
Group IV: Golimumab 200 mg	Golimumab 300 mg SC injection at Wk 0 followed by 200 mg SC injections every 4 Wks to Wk 52
Combined: Group III & IV	Combines Group III (golimumab 100 mg) and Group IV (golimumab 200 mg)

Measured Values

	Group I: Placebo	Group II: Golimumab 50 mg	Group III: Golimumab 100 mg	Group IV: Golimumab 200 mg	Combined: Group III & IV
Number of Participants Analyzed [units: participants]	**78**	**77**	**76**	**78**	**154**
Change From Baseline in Rescue Medication Use at 6 Months; Randomized Patients [units: Puffs/day] Median (Inter-Quartile Range)	**-0.54 (-1.57 to 0.50)**	**-0.71 (-1.71 to 0.52)**	**-0.29 (-1.79 to 0.26)**	**-0.14 (-1.67 to 0.67)**	**-0.21 (-1.71 to 0.57)**

Statistical Analysis 1 for Change From Baseline in Rescue Medication Use at 6 Months; Randomized Patients

Groups [1]	Group I: Placebo vs. Combined: Group III & IV
Method [2]	Kruskal-Wallis
P Value [3]	0.894

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis was that the endpoint for placebo is the same as that in the combined 100 mg and 200 mg golimumab.
[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 Rescue Medication Use at 6 Months; Randomized Patients

Groups [1]	Group I: Placebo vs. Group IV: Golimumab 200 mg
Method [2]	Kruskal-Wallis
P Value [3]	0.572

[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 Rescue Medication Use at 6 Months; Randomized Patients

Groups [1]	Group I: Placebo vs. Group III: Golimumab 100 mg
Method [2]	Kruskal-Wallis
P Value [3]	0.731

[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 Rescue Medication Use at 6 Months; Randomized Patients

Groups [1]	Group I: Placebo vs. Group II: Golimumab 50 mg
Method [2]	Kruskal-Wallis
P Value [3]	0.856

[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: Number of Severe Asthma Exacerbations Per Patient From Week 24 Through Week 52; Randomized Patients Who Did Not Discontinue Study Participation Prior to Week 24 [Time Frame: Week 24 to Week 52]

Measure Type	Secondary
Measure Title	

	Number of Severe Asthma Exacerbations Per Patient From Week 24 Through Week 52; Randomized Patients Who Did Not Discontinue Study Participation Prior to Week 24
Measure Description	The endpoint is the average number of severe asthma exacerbations per patient from Week (Wk) 24 through Wk 52 for the patients who did not discontinue study participation prior to Wk 24
Time Frame	Week 24 to Week 52
Safety Issue	Yes

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.
Analysis of this endpoint only includes patients (pts) who did not discontinue study participation prior to Wk 24. For the dropouts during the period between Wks 24- 52, worst case in similar pts was used as the number of severe exacerbations. Data from Wk 24-52 must be interpreted with caution as study agent was stopped at various study timepoints

Reporting Groups

	Description
Group I: Placebo	Placebo subcutaneous (SC) injections every 4 weeks (Wks) from Wk 0 to Wk 52
Group II: Golimumab 50 mg	Golimumab 75 milligram (mg) SC injection at Wk 0 followed by 50 mg SC injections every 4 Wks to Wk 52
Group III: Golimumab 100 mg	Golimumab 150 mg SC injection at Wk 0 followed by 100 mg SC injections every 4 Wks to Wk 52
Group IV: Golimumab 200 mg	Golimumab 300 mg SC injection at Wk 0 followed by 200 mg SC injections every 4 Wks to Wk 52
Combined: Group III & IV	Combines Group III (golimumab 100 mg) and Group IV (golimumab 200 mg)

Measured Values

	Group I: Placebo	**Group II: Golimumab 50 mg**	**Group III: Golimumab 100 mg**	**Group IV: Golimumab 200 mg**	**Combined: Group III & IV**
Number of Participants Analyzed [units: participants]	**77**	**68**	**71**	**74**	**145**
Number of Severe Asthma Exacerbations Per Patient From Week 24 Through Week 52; Randomized Patients Who Did Not Discontinue Study Participation Prior to Week 24 [units: Events per patient from Wk 24 thru Wk 52] Mean (Standard Deviation)	**0.6 (1.02)**	**0.8 (1.23)**	**0.9 (1.18)**	**0.8 (1.01)**	**0.9 (1.09)**

Statistical Analysis 1 for Number of Severe Asthma Exacerbations Per Patient From Week 24 Through Week 52; Randomized Patients Who Did Not Discontinue Study Participation Prior to Week 24

Groups [1]	Group I: Placebo vs. Combined: Group III & IV
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.273

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis was that the endpoint for placebo is the same as that in the combined 100 mg and 200 mg golimumab.
[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 Severe Asthma Exacerbations Per Patient From Week 24 Through Week 52; Randomized Patients Who Did Not Discontinue Study Participation Prior to Week 24

Groups [1]	Group I: Placebo vs. Group IV: Golimumab 200 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.382

[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 Severe Asthma Exacerbations Per Patient From Week 24 Through Week 52; Randomized Patients Who Did Not Discontinue Study Participation Prior to Week 24

Groups [1]	Group I: Placebo vs. Group III: Golimumab 100 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.350

[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 Severe Asthma Exacerbations Per Patient From Week 24 Through Week 52; Randomized Patients Who Did Not Discontinue Study Participation Prior to Week 24

Groups [1]	Group I: Placebo vs. Group II: Golimumab 50 mg
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.341

[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 Oral Corticosteroids Dose at Week 52; Randomized Patients Who Received Oral Corticosteroids at Baseline [Time Frame: Baseline and Week 52]

Measure Type	Secondary
Measure Title	Change From Baseline in Oral Corticosteroids Dose at Week 52; Randomized Patients Who Received Oral Corticosteroids at Baseline
Measure Description	The endpoint is the change from baseline at Week (Wk) 52 in oral corticosteroids (OCS) dose for the randomized patients who received OCS at baseline.
Time Frame	Baseline and Week 52
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.

Analysis of this endpoint includes only pts who received OCS at baseline.Wk 52 OCS dose is the daily OCS dose in the last period, defined as between 2 consecutive visits, in which no change in total daily dose of OCS occurred, prior to Wk 52 visit.Data from Wk 24-52 must be interpreted with caution as study agent was stopped at various timepoints.

Reporting Groups

	Description
Group I: Placebo	Placebo subcutaneous (SC) injections every 4 weeks (Wks) from Wk 0 to Wk 52
Group II: Golimumab 50 mg	Golimumab 75 mg SC injection at Wk 0 followed by 50 mg SC injections every 4 Wks to Wk 52
Group III: Golimumab 100 mg	Golimumab 150 mg SC injection at Wk 0 followed by 100 mg SC injections every 4 Wks to Wk 52
Group IV: Golimumab 200 mg	Golimumab 300 mg SC injection at Wk 0 followed by 200 mg SC injections every 4 Wks to Wk 52
Combined: Group III & IV	Combines Group III (golimumab 100 mg) and Group IV (golimumab 200 mg)

Measured Values

	Group I: Placebo	Group II: Golimumab 50 mg	Group III: Golimumab 100 mg	Group IV: Golimumab 200 mg	Combined: Group III & IV
Number of Participants Analyzed [units: participants]	**25**	**25**	**25**	**24**	**49**
Change From Baseline in Oral Corticosteroids Dose at Week 52; Randomized Patients Who Received Oral Corticosteroids at Baseline [units: mg/day P. Eq.] Median (Inter-Quartile Range)	**-5.000 (-10.000 to 0.000)**	**0.000 (-5.000 to 0.000)**	**-4.550 (-10.000 to 0.000)**	**-3.750 (-10.000 to 0.000)**	**-4.550 (-10.000 to 0.000)**

Statistical Analysis 1 for Change From Baseline in Oral Corticosteroids Dose at Week 52; Randomized Patients Who Received Oral Corticosteroids at Baseline

Groups [1]	Group I: Placebo vs. Combined: Group III & IV
Method [2]	Wilcoxon (Mann-Whitney)
P Value [3]	0.986

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis was that the endpoint for placebo is the same as that in the combined 100 mg and 200 mg golimumab.
[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 Oral Corticosteroids Dose at Week 52; Randomized Patients Who Received Oral Corticosteroids at Baseline

Groups [1]	Group I: Placebo vs. Group IV: Golimumab 200 mg
Method [2]	Wilcoxon (Mann-Whitney)
P Value [3]	0.820

[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 Oral Corticosteroids Dose at Week 52; Randomized Patients Who Received Oral Corticosteroids at Baseline

Groups [1]	Group I: Placebo vs. Group III: Golimumab 100 mg
Method [2]	Wilcoxon (Mann-Whitney)
P Value [3]	0.858

[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 Oral Corticosteroids Dose at Week 52; Randomized Patients Who Received Oral Corticosteroids at Baseline

Groups [1]	Group I: Placebo vs. Group II: Golimumab 50 mg
Method [2]	Wilcoxon (Mann-Whitney)
P Value [3]	0.021

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

7. Secondary: Change From Baseline in Domiciliary Morning Peak Expiratory Flow Rate (PEFR) at 6 Months; Randomized Subjects [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Domiciliary Morning Peak Expiratory Flow Rate (PEFR) at 6 Months; Randomized Subjects
Measure Description	The endpoint is the change from baseline in domiciliary morning PEFR at Week 24. PEFR— Peak Expiratory Flow Rate (PEFR): A measure of the speed of exhalation. The data were collected in the eDiary which was issued to each participant at screening. PEFR was collected morning and evening each day of the study.
Time Frame	Baseline to Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis of this endpoint uses intent-to-treat population. Missing data were imputed using last observation carried forward (LOCF).

Reporting Groups

	Description
Group I: Placebo	Placebo subcutaneous (SC) injections every 4 weeks (Wks) from week (Wk) 0 to Wk 52
Group II: Golimumab 50 mg	Golimumab 75 mg SC injection at Wk 0 followed by 50 mg SC injections every 4 Wks to Wk 52
Group III: Golimumab 100 mg	Golimumab 150 mg SC injection at Wk 0 followed by 100 mg SC injections every 4 Wks to Wk 52

Group IV: Golimumab 200 mg	Golimumab 300 mg SC injection at Wk 0 followed by 200 mg SC injections every 4 Wks to Wk 52
Combined: Group III & IV	Combines Group III (golimumab 100 mg) and Group IV (golimumab 200 mg)

Measured Values

	Group I: Placebo	Group II: Golimumab 50 mg	Group III: Golimumab 100 mg	Group IV: Golimumab 200 mg	Combined: Group III & IV
Number of Participants Analyzed [units: participants]	**78**	**77**	**76**	**78**	**154**
Change From Baseline in Domiciliary Morning Peak Expiratory Flow Rate (PEFR) at 6 Months; Randomized Subjects [units: L/min] Mean (Standard Deviation)	**4.730 (60.9136)**	**8.102 (58.0602)**	**3.488 (60.1336)**	**2.475 (59.7923)**	**2.975 (59.7668)**

Statistical Analysis 1 for Change From Baseline in Domiciliary Morning Peak Expiratory Flow Rate (PEFR) at 6 Months; Randomized Subjects

Groups [1]	Group I: Placebo vs. Combined: Group III & IV
Method [2]	ANOVA
P Value [3]	0.833

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis was that the endpoint for placebo is the same as that in the combined 100 mg and 200 mg golimumab.
[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 Domiciliary Morning Peak Expiratory Flow Rate (PEFR) at 6 Months; Randomized Subjects

Groups [1]	Group I: Placebo vs. Group IV: Golimumab 200 mg
Method [2]	ANOVA
P Value [3]	0.814

[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 Domiciliary Morning Peak Expiratory Flow Rate (PEFR) at 6 Months; Randomized Subjects

Groups [1]	Group I: Placebo vs. Group III: Golimumab 100 mg
Method [2]	ANOVA
P Value [3]	0.897

[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 Domiciliary Morning Peak Expiratory Flow Rate (PEFR) at 6 Months; Randomized Subjects

Groups [1]	Group I: Placebo vs. Group II: Golimumab 50 mg
Method [2]	ANOVA
P Value [3]	0.726

[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	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Group I: Placebo	Placebo subcutaneous (SC) injections every 4 wks from Wk 0 to Wk 52
Group II: Golimumab 50 mg	Golimumab (CNTO148) 75 mg SC injection at Wk 0 followed by 50 mg SC injections every 4 wks to Wk 52
Group III: Golimumab 100 mg	Golimumab 150 mg SC injection at Wk 0 followed by 100 mg SC injections every 4 wks to Wk 52
Group IV: Golimumab 200 mg	Golimumab 300 mg SC injection at Wk 0 followed by 200 mg SC injections every 4 wks to Wk 52

Serious Adverse Events

	Group I: Placebo	**Group II: Golimumab 50 mg**	**Group III: Golimumab 100 mg**	**Group IV: Golimumab 200 mg**
Total, serious adverse events				
# participants affected / at risk	**16/78 (20.51%)**	**24/75 (32.00%)**	**24/78 (30.77%)**	**22/78 (28.21%)**
Blood and lymphatic system disorders				
Anaemia † 1				
# participants affected / at risk	**0/78 (0.00%)**	**1/75 (1.33%)**	**0/78 (0.00%)**	**0/78 (0.00%)**
Cardiac disorders				
Myocardial infarction † 1				
# participants affected / at risk	**0/78 (0.00%)**	**0/75 (0.00%)**	**0/78 (0.00%)**	**2/78 (2.56%)**
Atrial fibrillation † 1				
# participants affected / at risk	**0/78 (0.00%)**	**0/75 (0.00%)**	**0/78 (0.00%)**	**1/78 (1.28%)**
Pericarditis † 1				
# participants affected / at risk	**0/78 (0.00%)**	**0/75 (0.00%)**	**0/78 (0.00%)**	**1/78 (1.28%)**
Eye disorders				
Retinal detachment † 1				
# participants affected / at risk	**1/78 (1.28%)**	**0/75 (0.00%)**	**0/78 (0.00%)**	**0/78 (0.00%)**

Vision blurred [†1]				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	0/78 (0.00%)
Gastrointestinal disorders				
Abdominal pain [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Dysphagia [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Enterocolitis [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Gastric haemorrhage [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Intestinal obstruction [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Lower gastrointestinal haemorrhage [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Pancreatitis acute [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Pneumatosis intestinalis [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Small intestinal obstruction [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Stomatitis [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Abdominal hernia [†1]				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	0/78 (0.00%)
Inguinal hernia [†1]				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	0/78 (0.00%)
General disorders				
Chest pain [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	2/78 (2.56%)
Pyrexia [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	1/78 (1.28%)
Hyperthermia [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Hepatobiliary disorders				
Cholelithiasis [†1]				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	0/78 (0.00%)
Immune system disorders				
Staphylococcal bacteraemia [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Serum sickness [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Infections and infestations				
Pneumonia [†1]				
# participants affected / at risk	1/78 (1.28%)	3/75 (4.00%)	5/78 (6.41%)	2/78 (2.56%)
Cellulitis [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	1/78 (1.28%)	2/78 (2.56%)
Sepsis [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	2/78 (2.56%)

Bacteraemia [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Bronchitis [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Bursitis infective [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Choriomeningitis lymphocytic [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Diverticulitis [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Escherichia bacteraemia [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Gastroenteritis [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Gastrointestinal infection [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Herpes simplex [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Oral candidiasis [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Pyelonephritis [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Septic shock [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Sinusitis [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Tonsillitis [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Tuberculosis [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Urinary tract infection [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Lower respiratory tract infection [†1]				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	0/78 (0.00%)
Postoperative wound infection [†1]				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	0/78 (0.00%)
Injury, poisoning and procedural complications				
Procedural nausea [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Metabolism and nutrition disorders				
Dehydration [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	1/78 (1.28%)	0/78 (0.00%)
Diabetes mellitus [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	1/78 (1.28%)
Diabetic ketoacidosis [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Gout [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Musculoskeletal and connective tissue disorders				

Back pain [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	1/78 (1.28%)	0/78 (0.00%)
Bursitis [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Osteoarthritis [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
B-cell lymphoma [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Basal cell carcinoma [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Breast cancer [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Cervix carcinoma [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Malignant melanoma [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Metastases to lung [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Metastases to lymph nodes [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Prostatic adenoma [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Renal cell carcinoma stage unspecified [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Nervous system disorders				
Syncope [†1]				
# participants affected / at risk	1/78 (1.28%)	1/75 (1.33%)	1/78 (1.28%)	0/78 (0.00%)
Headache [†1]				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Hypoaesthesia [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Pregnancy, puerperium and perinatal conditions				
Abortion spontaneous [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	1/78 (1.28%)
Pregnancy [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Psychiatric disorders				
Borderline personality disorder [†1]				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	0/78 (0.00%)
Renal and urinary disorders				
Nephrolithiasis [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Reproductive system and breast disorders				
Breast mass [†1]				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Metrorrhagia [†1]				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)

Prostatitis † 1				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)
Respiratory, thoracic and mediastinal disorders				
Asthma † 1				
# participants affected / at risk	7/78 (8.97%)	12/75 (16.00%)	6/78 (7.69%)	9/78 (11.54%)
Diffuse panbronchiolitis † 1				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Pneumonitis † 1				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Pulmonary embolism † 1				
# participants affected / at risk	0/78 (0.00%)	1/75 (1.33%)	0/78 (0.00%)	0/78 (0.00%)
Respiratory failure † 1				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Dyspnoea † 1				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	0/78 (0.00%)
Nasal polyps † 1				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	0/78 (0.00%)
Pleurisy † 1				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	0/78 (0.00%)
Respiratory distress † 1				
# participants affected / at risk	1/78 (1.28%)	0/75 (0.00%)	0/78 (0.00%)	0/78 (0.00%)
Skin and subcutaneous tissue disorders				
Eczema † 1				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	1/78 (1.28%)	0/78 (0.00%)
Vascular disorders				
Deep vein thrombosis † 1				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	0/78 (0.00%)	1/78 (1.28%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA10.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Group I: Placebo	Placebo subcutaneous (SC) injections every 4 wks from Wk 0 to Wk 52
Group II: Golimumab 50 mg	Golimumab (CNTO148) 75 mg SC injection at Wk 0 followed by 50 mg SC injections every 4 wks to Wk 52
Group III: Golimumab 100 mg	Golimumab 150 mg SC injection at Wk 0 followed by 100 mg SC injections every 4 wks to Wk 52
Group IV: Golimumab 200 mg	Golimumab 300 mg SC injection at Wk 0 followed by 200 mg SC injections every 4 wks to Wk 52

Other Adverse Events

	Group I: Placebo	Group II: Golimumab 50 mg	Group III: Golimumab 100 mg	Group IV: Golimumab 200 mg

Total, other (not including serious) adverse events				
# participants affected / at risk	**75/78 (96.15%)**	**68/75 (90.67%)**	**75/78 (96.15%)**	**75/78 (96.15%)**
Gastrointestinal disorders				
Nausea [†1]				
# participants affected / at risk	**1/78 (1.28%)**	**2/75 (2.67%)**	**6/78 (7.69%)**	**3/78 (3.85%)**
Abdominal pain upper [†1]				
# participants affected / at risk	**1/78 (1.28%)**	**2/75 (2.67%)**	**1/78 (1.28%)**	**4/78 (5.13%)**
Diarrhoea [†1]				
# participants affected / at risk	**5/78 (6.41%)**	**2/75 (2.67%)**	**1/78 (1.28%)**	**4/78 (5.13%)**
General disorders				
Injection site erythema [†1]				
# participants affected / at risk	**0/78 (0.00%)**	**2/75 (2.67%)**	**4/78 (5.13%)**	**4/78 (5.13%)**
Pyrexia [†1]				
# participants affected / at risk	**1/78 (1.28%)**	**0/75 (0.00%)**	**4/78 (5.13%)**	**4/78 (5.13%)**
Chest pain [†1]				
# participants affected / at risk	**5/78 (6.41%)**	**0/75 (0.00%)**	**1/78 (1.28%)**	**1/78 (1.28%)**
Infections and infestations				
Sinusitis [†1]				
# participants affected / at risk	**9/78 (11.54%)**	**19/75 (25.33%)**	**17/78 (21.79%)**	**10/78 (12.82%)**
Upper respiratory tract infection [†1]				
# participants affected / at risk	**16/78 (20.51%)**	**7/75 (9.33%)**	**14/78 (17.95%)**	**12/78 (15.38%)**
Nasopharyngitis [†1]				
# participants affected / at risk	**10/78 (12.82%)**	**9/75 (12.00%)**	**8/78 (10.26%)**	**12/78 (15.38%)**
Bronchitis [†1]				
# participants affected / at risk	**8/78 (10.26%)**	**4/75 (5.33%)**	**13/78 (16.67%)**	**10/78 (12.82%)**
Rhinitis [†1]				
# participants affected / at risk	**5/78 (6.41%)**	**3/75 (4.00%)**	**5/78 (6.41%)**	**6/78 (7.69%)**
Oral candidiasis [†1]				
# participants affected / at risk	**2/78 (2.56%)**	**3/75 (4.00%)**	**4/78 (5.13%)**	**4/78 (5.13%)**
Influenza [†1]				
# participants affected / at risk	**4/78 (5.13%)**	**1/75 (1.33%)**	**5/78 (6.41%)**	**4/78 (5.13%)**
Pneumonia [†1]				
# participants affected / at risk	**3/78 (3.85%)**	**4/75 (5.33%)**	**3/78 (3.85%)**	**3/78 (3.85%)**
Urinary tract infection [†1]				
# participants affected / at risk	**1/78 (1.28%)**	**1/75 (1.33%)**	**1/78 (1.28%)**	**5/78 (6.41%)**
Pharyngitis [†1]				
# participants affected / at risk	**0/78 (0.00%)**	**1/75 (1.33%)**	**1/78 (1.28%)**	**4/78 (5.13%)**
Acute sinusitis [†1]				
# participants affected / at risk	**7/78 (8.97%)**	**2/75 (2.67%)**	**1/78 (1.28%)**	**1/78 (1.28%)**
Injury, poisoning and procedural complications				
Contusion [†1]				
# participants affected / at risk	**1/78 (1.28%)**	**1/75 (1.33%)**	**4/78 (5.13%)**	**3/78 (3.85%)**
Musculoskeletal and connective tissue disorders				
Back pain [†1]				
# participants affected / at risk	**4/78 (5.13%)**	**4/75 (5.33%)**	**6/78 (7.69%)**	**3/78 (3.85%)**
Arthralgia [†1]				
# participants affected / at risk	**2/78 (2.56%)**	**5/75 (6.67%)**	**4/78 (5.13%)**	**3/78 (3.85%)**

Pain in extremity †1				
# participants affected / at risk	3/78 (3.85%)	4/75 (5.33%)	4/78 (5.13%)	3/78 (3.85%)
Myalgia †1				
# participants affected / at risk	1/78 (1.28%)	1/75 (1.33%)	4/78 (5.13%)	3/78 (3.85%)
Nervous system disorders				
Headache †1				
# participants affected / at risk	5/78 (6.41%)	5/75 (6.67%)	6/78 (7.69%)	6/78 (7.69%)
Migraine †1				
# participants affected / at risk	0/78 (0.00%)	2/75 (2.67%)	0/78 (0.00%)	4/78 (5.13%)
Respiratory, thoracic and mediastinal disorders				
Asthma †1				
# participants affected / at risk	71/78 (91.03%)	64/75 (85.33%)	69/78 (88.46%)	72/78 (92.31%)
Cough †1				
# participants affected / at risk	3/78 (3.85%)	2/75 (2.67%)	5/78 (6.41%)	3/78 (3.85%)
Productive cough †1				
# participants affected / at risk	4/78 (5.13%)	2/75 (2.67%)	4/78 (5.13%)	3/78 (3.85%)
Wheezing †1				
# participants affected / at risk	4/78 (5.13%)	2/75 (2.67%)	3/78 (3.85%)	4/78 (5.13%)
Dyspnoea †1				
# participants affected / at risk	3/78 (3.85%)	0/75 (0.00%)	4/78 (5.13%)	4/78 (5.13%)
Pharyngolaryngeal pain †1				
# participants affected / at risk	4/78 (5.13%)	3/75 (4.00%)	4/78 (5.13%)	1/78 (1.28%)
Nasal polyps †1				
# participants affected / at risk	0/78 (0.00%)	5/75 (6.67%)	0/78 (0.00%)	2/78 (2.56%)
Dysphonia †1				
# participants affected / at risk	0/78 (0.00%)	0/75 (0.00%)	4/78 (5.13%)	2/78 (2.56%)
Skin and subcutaneous tissue disorders				
Erythema †1				
# participants affected / at risk	2/78 (2.56%)	2/75 (2.67%)	4/78 (5.13%)	2/78 (2.56%)
Rash †1				
# participants affected / at risk	4/78 (5.13%)	1/75 (1.33%)	4/78 (5.13%)	3/78 (3.85%)
Eczema †1				
# participants affected / at risk	5/78 (6.41%)	2/75 (2.67%)	2/78 (2.56%)	3/78 (3.85%)
Pruritus †1				
# participants affected / at risk	4/78 (5.13%)	1/75 (1.33%)	1/78 (1.28%)	1/78 (1.28%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

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

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** Generally, the only disclosure restriction on the PI is that the sponsor has 60 days to review results communications prior to public release and can embargo communications regarding trial results for a period that does not exceed 180 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

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):

Wenzel SE, Barnes PJ, Bleecker ER, Bousquet J, Busse W, Dahlén SE, Holgate ST, Meyers DA, Rabe KF, Antczak A, Baker J, Horvath I, Mark Z, Bernstein D, Kerwin E, Schlenker-Herceg R, Lo KH, Watt R, Barnathan ES, Chanez P; T03 Asthma Investigators. A randomized, double-blind, placebo-controlled study of tumor necrosis factor-alpha blockade in severe persistent asthma. Am J Respir Crit Care Med. 2009 Apr 1;179(7):549-58. doi: 10.1164/rccm.200809-1512OC. Epub 2009 Jan 8.

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