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Comment Period Extended to 3/23/2015 for Notice of Proposed Rulemaking (NPRM) for FDAAA 801 and NIH Draft Reporting Policy for NIH-Funded Trials

Trial record **1 of 1** for: 2009-010714-30

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A Study to Evaluate the Safety and Effectiveness of Ustekinumab or Golimumab Administered Subcutaneously (SC) in Patients With Sarcoidosis

This study has been completed.

Sponsor:
Centocor, Inc.

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

ClinicalTrials.gov Identifier:
NCT00955279

First received: August 6, 2009
Last updated: June 18, 2014
Last verified: June 2014
History of Changes

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

Results First Received: June 18, 2014

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:	Sarcoidosis
Interventions:	Drug: Placebo Drug: Golimumab Drug: Ustekinumab

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Placebo	Matching Placebo was administered subcutaneously (injected under the skin by way of a needle) every 4 weeks up to Week 24.
Golimumab	Golimumab was administered subcutaneously at a dose of 200 milligram (mg) at Week 0 and thereafter at a dose of 100 mg every 4 weeks up to Week 24.
Ustekinumab	Ustekinumab was administered subcutaneously at a dose of 180 mg at Week 0 and thereafter at a dose of 90 mg at Week 8, 16 and 24 and matching Placebo was administered subcutaneously at Week 4, 12 and 20.

Participant Flow: Overall Study

	Placebo	Golimumab	Ustekinumab
STARTED	58	55	60
COMPLETED	55	51	52
NOT COMPLETED	3	4	8
Unspecified	0	0	3
Death	1	1	1
Lost to Follow-up	0	3	1
Withdrawal by Subject	2	0	3

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Placebo	Matching Placebo was administered subcutaneously (injected under the skin by way of a needle) every 4 weeks up to Week 24.
Golimumab	Golimumab was administered subcutaneously at a dose of 200 milligram (mg) at Week 0 and thereafter at a dose of 100 mg every 4 weeks up to Week 24.
Ustekinumab	Ustekinumab was administered subcutaneously at a dose of 180 mg at Week 0 and thereafter at a dose of 90 mg at Week 8, 16 and 24 and matching Placebo was administered subcutaneously at Week 4, 12 and 20.
Total	Total of all reporting groups

Baseline Measures

	Placebo	Golimumab	Ustekinumab	Total
Number of Participants [units: participants]	58	55	60	173
Age [units: Years] Mean ± Standard Deviation	49.5 ± 9.51	50.0 ± 9.44	49.8 ± 10.17	49.8 ± 9.67
Gender [units: participants]				
Female	29	27	29	85
Male	29	28	31	88
Number of Participants by stratification factors [1] [units: participants]				
Both Pulmonary and Skin	6	4	7	17
Pulmonary Only	38	38	39	115
Skin Only	14	13	14	41

[1] Participant allocation to treatment group was performed by interactive voice response system (IVRS) using a permuted block randomization stratified by baseline disease organ involvement (participants with pulmonary involvement only, participants with skin involvement only, and participants with both pulmonary and skin involvement) and prior use of anti-Tumor necrosis factor (TNF) biological therapy (yes or no).

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Percent-predicted Forced Vital Capacity (FVC) at Week 16 [Time Frame: Baseline (Day 1) and Week 16]

Measure Type	Primary
Measure Title	Change From Baseline in Percent-predicted Forced Vital Capacity (FVC) at Week 16
Measure Description	Forced vital capacity (FVC) is a standard pulmonary function test used to quantify respiratory muscle weakness . FVC was the volume of air that can forcibly be blown out after full inspiration in the upright position, measured in liters. Predicted forced vital capacity is based on a formula using sex, age and height of a person, and is an estimate of healthy lung capacity. Percent of predicted FVC = (observed value)/(predicted value) * 100%. Change was calculated as the value at Week 16 minus the baseline value.
Time Frame	Baseline (Day 1) and Week 16
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.
Modified intent-to-treat (mITT) population included all the participants who were randomized and who received at least 1 dose of study medication.

Reporting Groups

	Description
Placebo	Matching Placebo was administered subcutaneously (injected under the skin by way of a needle) every 4 weeks up to Week 24.
Golimumab	Golimumab was administered subcutaneously at a dose of 200 milligram (mg) at Week 0 and thereafter at a dose of 100 mg every 4 weeks up to Week 24.
Ustekinumab	Ustekinumab was administered subcutaneously at a dose of 180 mg at Week 0 and thereafter at a dose of 90 mg at Week 8, 16 and 24 and matching Placebo was administered subcutaneously at Week 4, 12 and 20.

Measured Values

	Placebo	Golimumab	Ustekinumab
Number of Participants Analyzed [units: participants]	**44**	**42**	**46**
Change From Baseline in Percent-predicted Forced Vital Capacity (FVC) at Week 16 [units: percent of predicted FVC] Least Squares Mean ± Standard Error	**2.02 ± 1.350**	**1.15 ± 1.413**	**-0.15 ± 1.279**

Statistical Analysis 1 for Change From Baseline in Percent-predicted Forced Vital Capacity (FVC) at Week 16

Groups [1]	Placebo vs. Golimumab
Method [2]	ANCOVA
P Value [3]	0.543

[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 Percent-predicted Forced Vital Capacity (FVC) at Week 16

Groups [1]	Placebo vs. Ustekinumab
Method [2]	ANCOVA
P Value [3]	0.126

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

2. Secondary: Change From Baseline in 6-minute Walk Distance at Week 28 [Time Frame: Baseline (Day 1) and Week 28]

Measure Type	Secondary
Measure Title	Change From Baseline in 6-minute Walk Distance at Week 28
Measure Description	Change from Baseline in 6-minute walk distance at Week 28 was calculated as 6-minute walk distance at Week 28 minus 6-minute walk distance at Baseline. The 6-minute walk distance was the total distance walked during the 6-minute walk test.
Time Frame	Baseline (Day 1) and Week 28
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.
mITT population included all the participants who were randomized and who received at least 1 dose of study medication.

Reporting Groups

	Description
Placebo	Matching Placebo was administered subcutaneously (injected under the skin by way of a needle) every 4 weeks up to Week 24.
Golimumab	Golimumab was administered subcutaneously at a dose of 200 milligram (mg) at Week 0 and thereafter at a dose of 100 mg every 4 weeks up to Week 24.
Ustekinumab	Ustekinumab was administered subcutaneously at a dose of 180 mg at Week 0 and thereafter at a dose of 90 mg at Week 8, 16 and 24 and matching Placebo was administered subcutaneously at Week 4, 12 and 20.

Measured Values

	Placebo	**Golimumab**	**Ustekinumab**
Number of Participants Analyzed [units: participants]	**44**	**42**	**46**
Change From Baseline in 6-minute Walk Distance at Week 28 [units: meters] Least Squares Mean ± Standard Error	**14.52 ± 14.223**	**12.53 ± 14.919**	**-13.22 ± 13.584**

Statistical Analysis 1 for Change From Baseline in 6-minute Walk Distance at Week 28

Groups [1]	Placebo vs. Golimumab
Method [2]	Linear Contrasts Test
P Value [3]	0.896

[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 6-minute Walk Distance at Week 28

Groups [1]	Placebo vs. Ustekinumab
Method [2]	Linear Contrasts Test
P Value [3]	0.063

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

3. Secondary: Change From Baseline in the St. George's Respiratory Questionnaire (SGRQ) Total Score at Week 28 [Time Frame: Baseline (Day 1) and Week 28]

Measure Type	Secondary
Measure Title	Change From Baseline in the St. George's Respiratory Questionnaire (SGRQ) Total Score at Week 28
Measure Description	St. George's Respiratory Questionnaire (SGRQ) is a health related quality of life questionnaire consisting of 51 items in three components: symptoms, activity, and impacts. The lowest possible value is zero and the highest 100. Higher values correspond to greater impairment in quality of life. Change from Baseline was calculated as the value at Week 28 minus value at Baseline.
Time Frame	Baseline (Day 1) and Week 28
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.
mITT population included all the participants who were randomized and who received at least 1 dose of study medication.

Reporting Groups

	Description
Placebo	Matching Placebo was administered subcutaneously (injected under the skin by way of a needle) every 4 weeks up to Week 24.
Golimumab	Golimumab was administered subcutaneously at a dose of 200 milligram (mg) at Week 0 and thereafter at a dose of 100 mg every 4 weeks up to Week 24.
Ustekinumab	Ustekinumab was administered subcutaneously at a dose of 180 mg at Week 0 and thereafter at a dose of 90 mg at Week 8, 16 and 24 and matching Placebo was administered subcutaneously at Week 4, 12 and 20.

Measured Values

	Placebo	Golimumab	Ustekinumab
Number of Participants Analyzed [units: participants]	**44**	**42**	**46**
Change From Baseline in the St. George's Respiratory Questionnaire (SGRQ) Total Score at Week 28 [units: Units on a scale] Least Squares Mean ± Standard Error	**-9.50 ± 2.790**	**-6.86 ± 2.921**	**-4.25 ± 2.662**

Statistical Analysis 1 for Change From Baseline in the St. George's Respiratory Questionnaire (SGRQ) Total Score at Week 28

Groups [1]	Placebo vs. Golimumab
Method [2]	Linear Contrasts Test
P Value [3]	0.374

[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 the St. George's Respiratory Questionnaire (SGRQ) Total Score at Week 28

Groups [1]	Placebo vs. Ustekinumab
Method [2]	Linear Contrasts Test
P Value [3]	0.073

[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: Percentage of Responders With a Score of Less Than or Equal to 1 on Skin Physician's Global Assessment (SPGA) Scale [Time Frame: Week 28]

Measure Type	Secondary
Measure Title	Percentage of Responders With a Score of Less Than or Equal to 1 on Skin Physician's Global Assessment (SPGA) Scale
Measure Description	The SPGA is 7-point scale used to assess the condition of skin in participants. The physician checks the state of the skin and gives them score from 0 (clear) to 5 (severe). Higher scores indicate worsening of skin condition.
Time Frame	Week 28
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.
Secondary population included all the participants with chronic sarcoidosis with skin involvement who have received at least 1 dose of study medication.

Reporting Groups

	Description
Placebo	Matching Placebo was administered subcutaneously (injected under the skin by way of a needle) every 4 weeks up to Week 24.
Golimumab	Golimumab was administered subcutaneously at a dose of 200 milligram (mg) at Week 0 and thereafter at a dose of 100 mg every 4 weeks up to Week 24.
Ustekinumab	Ustekinumab was administered subcutaneously at a dose of 180 mg at Week 0 and thereafter at a dose of 90 mg at Week 8, 16 and 24 and matching Placebo was administered subcutaneously at Week 4, 12 and 20.

Measured Values

	Placebo	**Golimumab**	**Ustekinumab**
Number of Participants Analyzed [units: participants]	**20**	**17**	**21**
Percentage of Responders With a Score of Less Than or Equal to 1 on Skin Physician's Global Assessment (SPGA) Scale [units: Percentage of Participants]	**30.0**	**52.9**	**14.3**

Statistical Analysis 1 for Percentage of Responders With a Score of Less Than or Equal to 1 on Skin Physician's Global Assessment (SPGA) Scale

Groups [1]	Placebo vs. Golimumab
Method [2]	Fisher Exact
P Value [3]	0.1931

[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 Percentage of Responders With a Score of Less Than or Equal to 1 on Skin Physician's Global Assessment (SPGA) Scale

Groups [1]	Placebo vs. Ustekinumab
Method [2]	Fisher Exact
P Value [3]	0.2772

[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 Percent-predicted Forced Vital Capacity (FVC) at Week 28 [Time Frame: Baseline (Day 1) and Week 28]

Measure Type	Secondary
Measure Title	Change From Baseline in Percent-predicted Forced Vital Capacity (FVC) at Week 28
Measure Description	Forced vital capacity (FVC) is a standard pulmonary function test used to quantify respiratory muscle weakness. FVC is the volume of air that can forcibly be blown out after full inspiration in the upright position, measured in liters. Predicted forced vital capacity is based on a formula using sex, age and height of a person, and is an estimate of healthy lung capacity. Percent of predicted FVC = (observed value)/(predicted value) * 100%. Change is calculated as the value at week 28 minus the baseline value.
Time Frame	Baseline (Day 1) and Week 28
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.
mITT population included all the participants who were randomized and who received at least 1 dose of study medication.

Reporting Groups

	Description
Placebo	Matching Placebo was administered subcutaneously (injected under the skin by way of a needle) every 4 weeks up to Week 24.
Golimumab	Golimumab was administered subcutaneously at a dose of 200 milligram (mg) at Week 0 and thereafter at a dose of 100 mg every 4 weeks up to Week 24.
Ustekinumab	Ustekinumab was administered subcutaneously at a dose of 180 mg at Week 0 and thereafter at a dose of 90 mg at Week 8, 16 and 24 and matching Placebo was administered subcutaneously at Week 4, 12 and 20.

Measured Values

	Placebo	**Golimumab**	**Ustekinumab**
Number of Participants Analyzed [units: participants]	**44**	**42**	**46**
Change From Baseline in Percent-predicted Forced Vital Capacity (FVC) at Week 28 [units: percent of predicted FVC] Least Squares Mean ± Standard Error	**1.59 ± 1.621**	**0.29 ± 1.697**	**0.56 ± 1.536**

Statistical Analysis 1 for Change From Baseline in Percent-predicted Forced Vital Capacity (FVC) at Week 28

Groups [1]	Placebo vs. Golimumab
Method [2]	Linear Contrast Test
P Value [3]	0.451

[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 Percent-predicted Forced Vital Capacity (FVC) at Week 28

Groups [1]	Placebo vs. Ustekinumab
Method [2]	Linear Contrast Test
P Value [3]	0.546

[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	Baseline and Week 16
Additional Description	No text entered.

Reporting Groups

	Description
Placebo	Matching Placebo was administered subcutaneously (injected under the skin by way of a needle) every 4 weeks up to Week 24.
Golimumab	Golimumab was administered subcutaneously at a dose of 200 milligram (mg) at Week 0 and thereafter at a dose of 100 mg every 4 weeks up to Week 24.
Ustekinumab	Ustekinumab was administered subcutaneously at a dose of 180 mg at Week 0 and thereafter at a dose of 90 mg at Week 8, 16 and 24 and matching Placebo was administered subcutaneously at Week 4, 12 and 20.

Serious Adverse Events

	Placebo	**Golimumab**	**Ustekinumab**
Total, serious adverse events			
# participants affected / at risk	**9/58 (15.52%)**	**7/55 (12.73%)**	**10/60 (16.67%)**
Cardiac disorders			

Atrial fibrillation [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	1/60 (1.67%)
Pulseless electrical activity [*1]			
# participants affected / at risk	0/58 (0.00%)	0/55 (0.00%)	1/60 (1.67%)
Gastrointestinal disorders			
Abdominal pain upper [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Diabetic gastroparesis [*1]			
# participants affected / at risk	0/58 (0.00%)	0/55 (0.00%)	1/60 (1.67%)
Diverticular perforation [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
General disorders			
Pyrexia [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	0/60 (0.00%)
Sudden death [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Immune system disorders			
Sarcoidosis [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	1/60 (1.67%)
Infections and infestations			
Bronchitis [*1]			
# participants affected / at risk	1/58 (1.72%)	1/55 (1.82%)	0/60 (0.00%)
Nasopharyngitis [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	0/60 (0.00%)
Pneumonia [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	3/60 (5.00%)
Sepsis [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	0/60 (0.00%)
Septic shock [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	0/60 (0.00%)
Tuberculosis [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	0/60 (0.00%)
Abscess [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Acute sinusitis [*1]			
# participants affected / at risk	0/58 (0.00%)	0/55 (0.00%)	1/60 (1.67%)
Influenza [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Oesophageal candidiasis [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	1/60 (1.67%)
Injury, poisoning and procedural complications			
Radius fracture [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Skeletal injury [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)

Traumatic renal injury [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Investigations			
Psychiatric evaluation [*1]			
# participants affected / at risk	0/58 (0.00%)	0/55 (0.00%)	1/60 (1.67%)
Metabolism and nutrition disorders			
Obesity [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	0/60 (0.00%)
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	1/60 (1.67%)
Musculoskeletal chest pain [*1]			
# participants affected / at risk	0/58 (0.00%)	0/55 (0.00%)	1/60 (1.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Nervous system disorders			
Cerebral sarcoidosis [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Psychiatric disorders			
Mental status changes [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	0/60 (0.00%)
Affective disorder [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Confusional state [*1]			
# participants affected / at risk	0/58 (0.00%)	0/55 (0.00%)	1/60 (1.67%)
Major depression [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Suicidal ideation [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Renal and urinary disorders			
Urethral disorder [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)
Respiratory, thoracic and mediastinal disorders			
Dyspnoea [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	0/60 (0.00%)
Pharyngeal cyst [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	0/60 (0.00%)
Pharyngeal haemorrhage [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	0/60 (0.00%)
Acute respiratory failure [*1]			
# participants affected / at risk	0/58 (0.00%)	0/55 (0.00%)	1/60 (1.67%)
Asthma [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	0/60 (0.00%)

Bronchial hyperreactivity *1			
# participants affected / at risk	**1/58 (1.72%)**	**0/55 (0.00%)**	**0/60 (0.00%)**
Bronchitis chronic *1			
# participants affected / at risk	**1/58 (1.72%)**	**0/55 (0.00%)**	**0/60 (0.00%)**
Chronic obstructive pulmonary disease *1			
# participants affected / at risk	**1/58 (1.72%)**	**0/55 (0.00%)**	**0/60 (0.00%)**
Pneumonitis *1			
# participants affected / at risk	**0/58 (0.00%)**	**0/55 (0.00%)**	**1/60 (1.67%)**
Pulmonary sarcoidosis *1			
# participants affected / at risk	**1/58 (1.72%)**	**0/55 (0.00%)**	**0/60 (0.00%)**
Vascular disorders			
Vasculitis *1			
# participants affected / at risk	**0/58 (0.00%)**	**0/55 (0.00%)**	**1/60 (1.67%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 15.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Baseline and Week 16
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	Matching Placebo was administered subcutaneously (injected under the skin by way of a needle) every 4 weeks up to Week 24.
Golimumab	Golimumab was administered subcutaneously at a dose of 200 milligram (mg) at Week 0 and thereafter at a dose of 100 mg every 4 weeks up to Week 24.
Ustekinumab	Ustekinumab was administered subcutaneously at a dose of 180 mg at Week 0 and thereafter at a dose of 90 mg at Week 8, 16 and 24 and matching Placebo was administered subcutaneously at Week 4, 12 and 20.

Other Adverse Events

	Placebo	**Golimumab**	**Ustekinumab**
Total, other (not including serious) adverse events			
# participants affected / at risk	**52/58 (89.66%)**	**49/55 (89.09%)**	**52/60 (86.67%)**
Gastrointestinal disorders			
Abdominal Pain *1			
# participants affected / at risk	**3/58 (5.17%)**	**0/55 (0.00%)**	**2/60 (3.33%)**
Abdominal Pain Upper *1			
# participants affected / at risk	**3/58 (5.17%)**	**1/55 (1.82%)**	**2/60 (3.33%)**
Constipation *1			
# participants affected / at risk	**2/58 (3.45%)**	**3/55 (5.45%)**	**3/60 (5.00%)**
Diarrhoea *1			

# participants affected / at risk	11/58 (18.97%)	6/55 (10.91%)	9/60 (15.00%)
Nausea [*1]			
# participants affected / at risk	6/58 (10.34%)	7/55 (12.73%)	8/60 (13.33%)
Vomiting [*1]			
# participants affected / at risk	7/58 (12.07%)	4/55 (7.27%)	6/60 (10.00%)
General disorders			
Chest Discomfort [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	3/60 (5.00%)
Chills [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	3/60 (5.00%)
Fatigue [*1]			
# participants affected / at risk	8/58 (13.79%)	11/55 (20.00%)	12/60 (20.00%)
Influenza Like Illness [*1]			
# participants affected / at risk	3/58 (5.17%)	2/55 (3.64%)	3/60 (5.00%)
Injection Site Erythema [*1]			
# participants affected / at risk	0/58 (0.00%)	4/55 (7.27%)	1/60 (1.67%)
Injection Site Pain [*1]			
# participants affected / at risk	1/58 (1.72%)	3/55 (5.45%)	1/60 (1.67%)
Injection Site Pruritus [*1]			
# participants affected / at risk	1/58 (1.72%)	3/55 (5.45%)	0/60 (0.00%)
Malaise [*1]			
# participants affected / at risk	0/58 (0.00%)	0/55 (0.00%)	3/60 (5.00%)
Non-Cardiac Chest Pain [*1]			
# participants affected / at risk	5/58 (8.62%)	0/55 (0.00%)	0/60 (0.00%)
Oedema Peripheral [*1]			
# participants affected / at risk	5/58 (8.62%)	8/55 (14.55%)	4/60 (6.67%)
Pyrexia [*1]			
# participants affected / at risk	3/58 (5.17%)	4/55 (7.27%)	5/60 (8.33%)
Immune system disorders			
Sarcoidosis [*1]			
# participants affected / at risk	3/58 (5.17%)	4/55 (7.27%)	10/60 (16.67%)
Infections and infestations			
Bronchitis [*1]			
# participants affected / at risk	8/58 (13.79%)	7/55 (12.73%)	8/60 (13.33%)
Herpes Zoster [*1]			
# participants affected / at risk	3/58 (5.17%)	1/55 (1.82%)	2/60 (3.33%)
Influenza [*1]			
# participants affected / at risk	0/58 (0.00%)	3/55 (5.45%)	1/60 (1.67%)
Nasopharyngitis [*1]			
# participants affected / at risk	2/58 (3.45%)	4/55 (7.27%)	9/60 (15.00%)
Oral Herpes [*1]			
# participants affected / at risk	3/58 (5.17%)	0/55 (0.00%)	1/60 (1.67%)
Respiratory Tract [*1]			
# participants affected / at risk	2/58 (3.45%)	4/55 (7.27%)	3/60 (5.00%)
Sinusitis [*1]			

# participants affected / at risk	9/58 (15.52%)	3/55 (5.45%)	5/60 (8.33%)
Upper Respiratory Tract Infection [*1]			
# participants affected / at risk	13/58 (22.41%)	6/55 (10.91%)	10/60 (16.67%)
Urinary Tract Infection [*1]			
# participants affected / at risk	3/58 (5.17%)	1/55 (1.82%)	0/60 (0.00%)
Viral Upper Respiratory Tract Infection [*1]			
# participants affected / at risk	1/58 (1.72%)	0/55 (0.00%)	4/60 (6.67%)
Investigations			
Alanine Aminotransferase Increased [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	3/60 (5.00%)
Aspartate Aminotransferase Increased [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	3/60 (5.00%)
Weight Increased [*1]			
# participants affected / at risk	3/58 (5.17%)	1/55 (1.82%)	0/60 (0.00%)
Metabolism and nutrition disorders			
Diabetes Mellitus [*1]			
# participants affected / at risk	3/58 (5.17%)	0/55 (0.00%)	0/60 (0.00%)
Gout [*1]			
# participants affected / at risk	3/58 (5.17%)	2/55 (3.64%)	1/60 (1.67%)
Musculoskeletal and connective tissue disorders			
Arthralgia [*1]			
# participants affected / at risk	16/58 (27.59%)	13/55 (23.64%)	9/60 (15.00%)
Back Pain [*1]			
# participants affected / at risk	6/58 (10.34%)	6/55 (10.91%)	9/60 (15.00%)
Joint Swelling [*1]			
# participants affected / at risk	0/58 (0.00%)	3/55 (5.45%)	2/60 (3.33%)
Muscle Spasms [*1]			
# participants affected / at risk	2/58 (3.45%)	5/55 (9.09%)	5/60 (8.33%)
Musculoskeletal Chest Pain [*1]			
# participants affected / at risk	4/58 (6.90%)	1/55 (1.82%)	2/60 (3.33%)
Musculoskeletal Pain [*1]			
# participants affected / at risk	3/58 (5.17%)	2/55 (3.64%)	1/60 (1.67%)
Musculoskeletal Stiffness [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	4/60 (6.67%)
Myalgia [*1]			
# participants affected / at risk	1/58 (1.72%)	3/55 (5.45%)	2/60 (3.33%)
Neck Pain [*1]			
# participants affected / at risk	3/58 (5.17%)	2/55 (3.64%)	0/60 (0.00%)
Pain in Extremity [*1]			
# participants affected / at risk	11/58 (18.97%)	3/55 (5.45%)	8/60 (13.33%)
Nervous system disorders			
Burning Sensation [*1]			
# participants affected / at risk	0/58 (0.00%)	1/55 (1.82%)	3/60 (5.00%)
Headache [*1]			
# participants affected / at risk	12/58 (20.69%)	7/55 (12.73%)	12/60 (20.00%)

Migraine [*1]			
# participants affected / at risk	**3/58 (5.17%)**	**1/55 (1.82%)**	**0/60 (0.00%)**
Psychiatric disorders			
Depression [*1]			
# participants affected / at risk	**3/58 (5.17%)**	**2/55 (3.64%)**	**2/60 (3.33%)**
Respiratory, thoracic and mediastinal disorders			
Cough [*1]			
# participants affected / at risk	**15/58 (25.86%)**	**11/55 (20.00%)**	**13/60 (21.67%)**
Dyspnoea [*1]			
# participants affected / at risk	**11/58 (18.97%)**	**10/55 (18.18%)**	**4/60 (6.67%)**
Nasal Congestion [*1]			
# participants affected / at risk	**2/58 (3.45%)**	**1/55 (1.82%)**	**3/60 (5.00%)**
Oropharyngeal Pain [*1]			
# participants affected / at risk	**4/58 (6.90%)**	**2/55 (3.64%)**	**7/60 (11.67%)**
Productive Cough [*1]			
# participants affected / at risk	**2/58 (3.45%)**	**1/55 (1.82%)**	**4/60 (6.67%)**
Upper Respiratory Tract Congestion [*1]			
# participants affected / at risk	**3/58 (5.17%)**	**1/55 (1.82%)**	**1/60 (1.67%)**
Wheezing [*1]			
# participants affected / at risk	**4/58 (6.90%)**	**2/55 (3.64%)**	**4/60 (6.67%)**
Skin and subcutaneous tissue disorders			
Pruritus [*1]			
# participants affected / at risk	**3/58 (5.17%)**	**4/55 (7.27%)**	**4/60 (6.67%)**
Rash [*1]			
# participants affected / at risk	**6/58 (10.34%)**	**6/55 (10.91%)**	**6/60 (10.00%)**
Skin Lesion [*1]			
# participants affected / at risk	**8/58 (13.79%)**	**1/55 (1.82%)**	**6/60 (10.00%)**
Vascular disorders			
Hypertension [*1]			
# participants affected / at risk	**3/58 (5.17%)**	**0/55 (0.00%)**	**4/60 (6.67%)**

* Events were collected by non-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

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Senior Director
Organization: Johnson & Johnson Pharmaceutical Research & Development
e-mail: ClinicalTrialDisclosure@its.jnj.com

No publications provided by Centocor, Inc.

Publications automatically indexed to this study:

Crommelin HA, Vorselaars AD, van Moorsel CH, Korenromp IH, Deneer VH, Grutters JC. Anti-TNF therapeutics for the treatment of sarcoidosis. Immunotherapy. 2014;6(10):1127-43. doi: 10.2217/imt.14.65.

Judson MA, Baughman RP, Costabel U, Drent M, Gibson KF, Raghu G, Shigemitsu H, Barney JB, Culver DA, Hamzeh NY, Wijsenbeek MS, Albera C, Huizar I, Agarwal P, Brodmerkel C, Watt R, Barnathan ES. Safety and efficacy of ustekinumab or golimumab in patients with chronic sarcoidosis. Eur Respir J. 2014 Nov;44(5):1296-307. doi: 10.1183/09031936.00000914. Epub 2014 Jul 17.

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