

History of Changes for Study: NCT02181673

A Study of Golimumab in Participants With Active Psoriatic Arthritis

[Latest version \(submitted December 20, 2017\) on ClinicalTrials.gov](#)

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in red.
- Study additions are displayed in green.

Study Record Versions

Version	A	B	Submitted Date	Changes
1			July 2, 2014	None (earliest Version on record)
2			August 13, 2014	Study Status
3			September 24, 2014	Study Status
4			October 2, 2014	Recruitment Status, Study Status, Contacts/Locations and References
5			October 23, 2014	Contacts/Locations, Oversight and Study Status
6			November 13, 2014	Study Status
7			December 4, 2014	Study Status and Contacts/Locations
8			January 13, 2015	Study Status and Contacts/Locations
9			February 9, 2015	Study Status and Contacts/Locations
10			March 2, 2015	Contacts/Locations and Study Status
11			March 23, 2015	Contacts/Locations and Study Status
12			April 13, 2015	Study Status and Contacts/Locations
13			May 4, 2015	Study Status and Contacts/Locations
14			May 26, 2015	Contacts/Locations and Study Status
15			June 29, 2015	Contacts/Locations and Study Status
16			July 20, 2015	Study Status and Contacts/Locations
17			August 10, 2015	Study Status and Contacts/Locations
18			September 21, 2015	Contacts/Locations and Study Status
19			October 14, 2015	Contacts/Locations and Study Status
20			November 4, 2015	Contacts/Locations and Study Status
21			November 25, 2015	Contacts/Locations and Study Status
22			December 18, 2015	Contacts/Locations and Study Status
23			January 8, 2016	Study Status
24			January 29, 2016	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
25			<u>February 10, 2016</u>	Recruitment Status, Contacts/Locations, Study Status, Study Design and References
26			<u>March 2, 2016</u>	Study Status
27			<u>May 20, 2016</u>	Contacts/Locations and Study Status
28			<u>July 15, 2016</u>	Study Status, Outcome Measures and Conditions
29			<u>October 5, 2016</u>	Study Status
30			<u>January 23, 2017</u>	Study Status
31			<u>February 23, 2017</u>	Study Status
32			<u>April 20, 2017</u>	Recruitment Status, Study Status and Oversight ► Results Submission Events
33			<u>December 20, 2017</u>	Study Status, Outcome Measures, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow

Compare

Comparison Format:

- Merged
 Side-by-Side

Scroll up to access the controls

Study NCT02181673
Submitted Date: January 23, 2017 (v30)

Study Identification

Unique Protocol ID: CR103796

Brief Title: A Study of Golimumab in Participants With Active Psoriatic Arthritis

Official Title: A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, an Anti-TNF α Monoclonal Antibody Intravenously, in Subjects With Active Psoriatic Arthritis

Secondary IDs: 2014-000242-30 [EudraCT Number]

CNT0148PSA3001 [Janssen Research & Development, LLC]

Study Status

Record Verification: January 2017

Overall Status: Active, not recruiting

Study Start: September 2014

Primary Completion: May 2016 [Actual]

Study Completion: April 2017 [Anticipated]

First Submitted: July 2, 2014

First Submitted that Met QC Criteria: July 2, 2014

Met QC Criteria:

First Posted: July 4, 2014 [Estimate]

Certification/Extension: January 23, 2017

First Submitted:

Certification/Extension: January 23, 2017

First Submitted that Met QC Criteria:

Met QC Criteria:

Certification/Extension: January 24, 2017 [Estimate]

First Posted:

Last Update Submitted that Met QC Criteria: January 23, 2017

Met QC Criteria:

Last Update Posted: January 24, 2017 [Estimate]

Sponsor/Collaborators

Sponsor: Janssen Research & Development, LLC

Responsible Party: Sponsor

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: The purpose of this study is to evaluate the efficacy of intravenously (administration of a fluid into the vein) administered milligram per kilogram (mg/kg) in participants with active psoriatic arthritis (a chronic inflammatory arthritis that is associated with psoriasis).

Detailed Description: This is a Phase 3, multicenter (when more than one hospital or medical school team work on a medical research study) (study drug assigned by chance), double-blind (neither the researchers nor the participants know what treatment they are receiving), placebo-controlled (an inactive substance; a pretend treatment [with no drug in it] that is compared in a study to test if the drug has a real effect) study of golimumab compared with placebo in participants with active psoriatic arthritis. The study will include 4 phases: Screening phase (up to 6 weeks), Double-blind placebo-controlled phase (Week 0 to Week 24), treatment phase (Week 24 to Week 52), and Safety follow-up phase (8 weeks from last study drug administration). The study will be 60 weeks per participant. Eligible Participants will be randomly assigned to either Treatment Group 1: Placebo or Treatment Group 2: Golimumab. Participants randomized to Placebo Group, will receive intravenous infusions of placebo at Weeks 0, 4, 12 and 20. At Week 24, all participants receiving placebo will begin receiving intravenous infusions of golimumab 2 mg/kg at Week 0, 4 and thereafter every 8 weeks up to Week 52. Participants randomized to Golimumab Group, will receive intravenous infusions of golimumab 2 mg/kg at Week 0, 4 and thereafter every 8 weeks up to Week 52. At Week 24, participants randomized to Placebo Group will receive a placebo infusion to maintain the blind. The efficacy will be assessed primarily by measuring the percentage of participants who achieve a 20 percent improvement from baseline in the assessment used in active psoriatic arthritis. Participants' safety will be monitored throughout the study.

Conditions

Conditions: Arthritis, Psoriatic

Keywords: Psoriatic arthritis
Golimumab
Simponi

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Double (Participant, Investigator)

Allocation: Randomized

Enrollment: 480 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Placebo Comparator: Treatment Group 1: Placebo Participants will receive intravenous infusions of placebo at Weeks 0, 4, 12 and 20. At Week 24, all participants receiving placebo will begin receiving intravenous infusions of golimumab 2 milligram per kilogram (mg/kg) at Week 24, 28 and thereafter every 8 weeks up to Week 52.	Drug: Placebo Participants will receive intravenous infusions of placebo at Weeks 0, 4, 12 and 20 in treatment Group 1 and intravenous infusions of placebo at Week 24 to maintain the blind in treatment Group 2. Drug: Golimumab Participants will receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and thereafter every 8 weeks up to Week 52 in treatment Group 2 and intravenous infusions of golimumab (2mg/kg) at Week 24 and thereafter every 8 weeks up to Week 52 in treatment Group 1.
Experimental: Treatment Group 2: Golimumab Participants will receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and thereafter every 8 weeks up to Week 52. At Week 24, participants will receive a placebo infusion to maintain the blind.	Drug: Placebo Participants will receive intravenous infusions of placebo at Weeks 0, 4, 12 and 20 in treatment Group 1 and intravenous infusions of placebo at Week 24 to maintain the blind in treatment Group 2. Drug: Golimumab Participants will receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and thereafter every 8 weeks up to Week 52 in treatment Group 2 and intravenous infusions of golimumab (2mg/kg) at Week 24 and thereafter every 8 weeks up to Week 52 in treatment Group 1.

Outcome Measures

Primary Outcome Measures:

1. Percentage of Participants who Achieve an American College of Rheumatology (ACR) 20 Response at Week 14

The ACR 20 response is defined as greater or equal to ($\geq$) 20 percent (%) improvement from baseline in both swollen joint count (66 joints), count (66 joints) and $\geq$ 20% improvement from baseline in at least 3 of the following 5 assessments: Patient's assessment of pain (on a 0 to 10 cm scale), Patient's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Physician's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Patient's assessment of physical function as measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI) and measurement of C-reactive protein (CRP).

[Time Frame: Week 14]

Secondary Outcome Measures:

2. Change from baseline in the Disability Index of the Health Assessment Questionnaire (HAQ-DI) score at Week 14

The HAQ-DI assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, handling, gripping, and activities of daily living), each scored from 0 (no difficulty) to 3 (inability to perform a task).

[Time Frame: Baseline and Week 14]

3. Percentage of Participants who Achieve an ACR 50 Response at Week 14

The ACR 50 response is defined as: greater or equal to ($\geq$) 50 percent (%) improvement from baseline in both swollen joint count (66 joints), count (66 joints) and $\geq$ 50% improvement from baseline in at least 3 of the following 5 assessments: Patient's assessment of pain (on a 0 to 10 cm scale), Patient's Global Assessment of Disease Activity (on a 0 to 10 cm scale), Physician's Global Assessment of Disease Activity (on a 0 to 10 cm scale), assessment of physical function as measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI) and measurement of a reactive protein (CRP).

[Time Frame: Week 14]

4. Percentage of Participants achieving Psoriatic Area and Severity Index (PASI) 75 response at Week 14

The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy that is scored from 0 to 100. A response is defined as $\geq$ 75% improvement in PASI score from baseline.

[Time Frame: Week 14]

5. Change From Baseline in Total Modified Van Der Heijde-Sharp (vdH-S) Score at Week 24

The vdH-S score is the sum of joint erosion score and joint-space narrowing (JSN) score based on x-rays of both hands and both feet. The score ranges from 0 to 528 with higher scores indicating more joint damage. For the change from baseline, positive values show an increase in damage.

[Time Frame: Baseline and Week 24]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Have had psoriatic arthritis (PsA) for at least 6 months prior to the first administration of study agent
- Have a diagnosis of active PSA as defined by 5 or more swollen joints and 5 or more tender joints at Screening and C-reactive protein $\geq$ 0.6 milligram per deciliter (mg/dL) at Screening
- Have active plaque psoriasis or a documented history of plaque psoriasis
- Have active PSA despite current or previous disease-modifying antirheumatic drugs (DMARD) and/or nonsteroidal anti-inflammatory drug (NSAID) therapy. DMARD therapy is defined as taking a DMARD for at least 3 months, or DMARD intolerance. NSAID therapy is defined as taking an NSAID for at least 4 weeks or evidence of NSAID

Exclusion Criteria:

- Have other inflammatory diseases that might confound the evaluations of benefit of Golimumab therapy, including rheumatoid arthritis, ankylosing spondylitis, systemic lupus erythematosus, or Lyme disease
- Are pregnant, nursing, or planning a pregnancy or fathering a child while enrolled in the study or within 4 months of the last administration of study agent
- Have used any biologic agents that are targeted for reducing tumor necrosis factors (TNF) alpha, including but not limited to Infliximab, Etanercept, Adalimumab, Golimumab, and Certolizumab Pegol
- Have ever used cytotoxic drugs, including Chlorambucil, Cyclophosphamide, Nitrogen mustard, or other Alkylating agents

Contacts/Locations

Study Officials: Janssen Research & Development, LLC Clinical Trial

Study Director

Janssen Research & Development, LLC

Locations: United States, Arizona

Glendale, Arizona, United States

Mesa, Arizona, United States

United States, California

Huntington Beach, California, United States

Lakewood, California, United States

United States, Indiana

Granger, Indiana, United States

Indianapolis, Indiana, United States

United States, Louisiana

Monroe, Louisiana, United States

United States, Mississippi

Tupelo, Mississippi, United States

United States, Missouri

Saint Louis, Missouri, United States

United States, New York

Orchard Park, New York, United States

United States, North Carolina

Salisbury, North Carolina, United States

United States, Pennsylvania

Duncansville, Pennsylvania, United States

United States, Texas

Austin, Texas, United States

Australia

Daw Park, Australia

Maroochydore, Australia

Belarus

Gomel, Belarus

Grodno, Belarus

Minsk, Belarus

Vitebsk, Belarus

Canada, Newfoundland and Labrador

Saint-John's, Newfoundland and Labrador, Canada

Canada, Ontario

Waterloo, Ontario, Canada

Canada

Burlington, Canada

Germany

Bad Doberan, Germany

Berlin, Germany

Erfurt, Germany

Hamburg, Germany

Köln, Germany

Ratingen, Germany

Zerbst, Germany

Hungary

Balatonfüred, Hungary

Budapest, Hungary

Debrecen, Hungary

Heviz, Hungary

Kistarcsa, Hungary

Nyíregyháza, Hungary

Szombathely, Hungary

Lithuania

Alytus, Lithuania

Kaunas, Lithuania

Klaipeda, Lithuania

Siauliai, Lithuania

Vilnius, Lithuania

Poland

Bydgoszcz, Poland

Bytom, Poland

Czestochowa, Poland

Krakow, Poland

Lublin, Poland

Nadarzyn, Poland

Nowa Sól, Poland

Poznan, Poland

Warszawa, Poland

Wroclaw, Poland

Romania

Bucuresti, Romania

Constanta, Romania

Iasi, Romania

Ploiesti, Romania

Russian Federation

Kemerovo, Russian Federation

Korolev, Russian Federation

Krasnoyarsk, Russian Federation

Kursk, Russian Federation

Moscow, Russian Federation

Novosibirsk, Russian Federation

Orenburg, Russian Federation

Petrozavodsk, Russian Federation

Ryazan, Russian Federation

Saint Petersburg, Russian Federation

Saint-Petersburg, Russian Federation

Saratov, Russian Federation

Tomsk, Russian Federation

Tver, Russian Federation

Ulyanovsk, Russian Federation

Vladimir, Russian Federation

Yaroslavl, Russian Federation

Spain

Cordoba, Spain

Getafe, Spain

Sevilla, Spain

Ukraine

Chemihiv, Ukraine

Dnipropetrovsk, Ukraine

Kharkiv, Ukraine

Khmeltsky, Ukraine

Kyiv, Ukraine
Lviv, Ukraine
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