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Completed ⓘ

A Study of Golimumab in Participants With Active Ankylosing Spondylitis

ClinicalTrials.gov ID ⓘ NCT02186873

Sponsor ⓘ Janssen Research & Development, LLC

Information provided by ⓘ Janssen Research & Development, LLC (Responsible Party)

Last Update Posted ⓘ 2025-10-30

Record History Tab

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
- To view one version of the study record, click the submitted date.
- To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.
 - Data that is changed in the study record is color coded:
 - Deletions from the study record are shown crossed out in red highlights.
 - Additions to the study record are shown in green highlights.

☐	1	2014-07-08	• None (earliest version on record)
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Compare

			• Contacts/Locations
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Viewing **V24** (2015-10-27)

Version	Date submitted (YYYY-MM-DD)	Changes
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Study Details

Study Identification

Unique Protocol ID	CR103795
Brief Title	A Study of Golimumab in Participants With Active Ankylosing Spondylitis
Official Title	A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, an Anti-TNF α Monoclonal Antibody, Administered Intravenously, in Subjects With Active Ankylosing Spondylitis
Secondary IDs	CNT0148AKS3001, 2014-000241-74

Study Status

Record Verification	2015-10
Overall Status	Active, not recruiting
Study Start	2014-09
Primary Completion	2016-04 [Estimated]

Study Completion	2016-07 [Estimated]
First Submitted	2014-07-08
First Submitted that Met QC Criteria	2014-07-08
First Posted	2014-07-10 [Estimated]
Certification/Extension First Submitted	2016-07-19
Last Update Submitted that Met QC Criteria	2015-10-27
Last Update Posted	2015-10-29 [Estimated]

Sponsor/Collaborators

Sponsor	Janssen Research & Development, LLC
Responsible Party	Sponsor
Collaborators	

Version	Date submitted (YYYY-MM-DD)	Changes
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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 golimumab 2 milligram per kilogram (mg/kg) in participants with active ankylosing spondylitis (chronic inflammatory disease of unknown etiology that involves the sacroiliac joints, and often the axial skeleton, entheses, and peripheral joints).
Detailed Description	This is a Phase 3, multicenter (when more than one hospital or medical school team work on a medical research study), randomized (study drug assigned by chance), double-blind (neither the researchers nor the participants know what treatment the participant is receiving), placebo-controlled (an inactive substance; a pretend treatment [with no drug in it] that is compared in a clinical trial with a drug to test if the drug has a real effect) study of golimumab compared with placebo in participants with active ankylosing spondylitis. The study comprises of 4 phases: Screening phase (up to 6 weeks), Double-blind placebo-controlled phase (Week 0 to Week 16), Active treatment phase (Week 16 to Week 52), and Safety follow-up phase (8 weeks from last study

	drug administration). Total duration of 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 and 12. At Week 16, all participants receiving placebo will begin receiving intravenous infusions of golimumab (2 mg/kg) at Weeks 16, 20 and thereafter every 8 weeks up to Week 52. Participants randomized to Golimumab group, will receive intravenous infusions of golimumab 2 mg/kg at Weeks 0, 4 and thereafter every 8 weeks up to Week 52. At Week 16, participants randomized to golimumab group will receive a placebo infusion to maintain the blind. The efficacy will be assessed primarily by measuring percentage of participants who achieve a 20 percent improvement from baseline in the assessment in ankylosing spondylitis (ASAS) at Week 16. Participant's safety will be monitored throughout the study.
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Conditions

Condition	Ankylosing Spondylitis
Keywords	Ankylosing Spondylitis Golimumab SIMPONI

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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	208 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Placebo Comparator: Treatment Group 1: Placebo Participants will receive intravenous infusions of placebo at Weeks 0, 4 and 12. At Week 16, all participants receiving placebo will begin receiving intravenous infusions of golimumab 2	Drug: Placebo Participants will receive intravenous infusions of placebo at Weeks 0, 4 and 12 in treatment group 1 and intravenous

milligram per kilogram (mg/kg) at Weeks 16, 20 and thereafter every 8 weeks up to Week 52.	infusions of placebo at Week 16 to maintain the blind in treatment group 2. Drug: Golimumab Participants will receive intravenous infusions of golimumab 2mg/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 Weeks 16, 20 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 16, participants will receive a placebo infusion to maintain the blind.	Drug: Placebo - Participants will receive intravenous infusions of placebo at Weeks 0, 4 and 12 in treatment group 1 and intravenous infusions of placebo at Week 16 to maintain the blind in treatment group 2. Drug: Golimumab - Participants will receive intravenous infusions of golimumab 2mg/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 Weeks 16, 20 and thereafter every 8 weeks up to Week 52 in treatment group 1.

Outcome Measures

Primary Outcome Measures	1. Percentage of Participants Achieving a 20 Percent Improvement in Assessment in Ankylosing Spondylitis (ASAS 20) at Week 16 A 20 percent (%) improvement in response according to the criteria of ASAS International Working Group is defined as; Improvement of greater than or equal to ($\geq$) 20% from baseline and absolute improvement from baseline of at least 1 on a 0 to 10 centimeter (cm) scale in at least 3 of the following 4 domains: Patient's global assessment of disease activity (0 to 10 cm; 0=very well, 10=very poor), Total back pain (0 to 10 cm; 0=no pain, 10=most severe pain), Function (self-assessment represented as a mean (0 to 10 cm; 0=easy to 10=impossible) of 10 questions, 8 of which relate to the participant's functional anatomy and 2 of which relate to a participant's ability to cope with everyday life, Inflammation (0 to 10 cm; 0=none, 10=very severe); and absence of deterioration (worsening of $\geq$20% and at least 1 on a 0 to 10 cm scale) from baseline in the potential remaining domain. [Time Frame: Week 16]
Secondary Outcome Measures	1. Percentage of Participants Achieving a 40 Percent Improvement in Assessment in Ankylosing Spondylitis (ASAS 40) at Week 16 An ASAS 40 response is defined as $\geq$40% improvement in 3 of 4 domains: Patient's global assessment of disease activity (0 to 10 cm; 0=very well, 10=very poor), Total back pain (0 to 10 cm; 0=no pain, 10=most severe pain), Function (self-assessment represented as a mean (0 to 10 cm; 0=easy to 10=impossible) of 10 questions, 8 of which relate to the participant's functional anatomy and 2 of which relate to a participant's ability to cope with everyday life,

	Inflammation (0 to 10 cm; 0=none, 10=very severe) with an absolute improvement of at least 2 units on a 0 to 10 cm scale, and no deterioration in the remaining domain. [Time Frame: Week 16]
2.	Percentage of Participants With at Least 50 Percent Improvement From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at Week 16 The BASDAI is a self-assessment tool to determine disease activity using a VAS of 0-10 cm (0=none and 10=very severe) participant's answered 6 questions measuring fatigue, spinal pain, joint pain, enthesitis, and morning stiffness. The final BASDAI score calculates the individual assessments for a final score range of 0 to 10 cm; 0=best and 10=worst. [Time Frame: Week 16]
3.	Change From Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI) Score at Week 16 The BASFI is a participant's self-assessment represented as a mean (VAS 0 to 10 cm; 0=easy to 10=impossible) of 10 questions, each question rated on VAS 0 to 10 cm, 8 of which relate to the participant's functional anatomy and 2 of which relate to a participant's ability to cope with everyday life. [Time Frame: Baseline and Week 16]

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	Inclusion Criteria: - Participants with diagnosis of definite ankylosing spondylitis for at least 3 months based on modified New York radiographic and clinical criteria - Participants with symptoms of active disease at screening and at baseline - Participant has either an inadequate response to at least 2 non-steroidal anti-inflammatory drugs (NSAID) over a 4 week period in total with maximal recommended doses of NSAIDs, or is unable to receive a full 4 weeks of maximal NSAID therapy because of intolerance, toxicity, or contraindications to NSAIDs - Participants with C- reactive protein (CRP) level of greater than or equal to ($\geq$) 0.3 milligram per deciliter (mg/dL) at screening - Additional protocol-defined inclusion criteria apply Exclusion Criteria: - Participant with other inflammatory diseases that might confound the evaluations of benefit from the golimumab therapy - Pregnant or lactating females

	• Participants with chest radiograph within 3 months prior to the first administration of study agent that shows an abnormality suggestive of a malignancy or current active infection, including tuberculosis • Participants who had a serious infection (including but not limited to, hepatitis, pneumonia, sepsis, or pyelonephritis), or have been hospitalized for an infection, or have been treated with intravenous (IV) antibiotics for an infection within 2 months prior to first administration of study agent • Additional protocol-defined exclusion criteria apply
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Contacts/Locations

Central Contact Person	
Study Officials	• Name Janssen Research & Development, LLC Clinical Trial • Role Study Director • Affiliation Janssen Research & Development, LLC
Location	• Glendale, Arizona, United States • Mesa, Arizona, United States • La Palma, California, United States • Granger, Indiana, United States • St Louis, Missouri, United States • Orchard Park, New York, United States • Salisbury, North Carolina, United States • Middleburg Heights, Ohio, United States • Duncansville, Pennsylvania, United States • Austin, Texas, United States • Houston, Texas, United States • Maroochydore, Australia • St. John's, Newfoundland and Labrador, Canada • Burlington, Canada • Trois-Rivières, Canada • Bad Doberan, Germany • Berlin, Germany • Erfurt, Germany • Hamburg, Germany • Planegg, Germany • Ratingen, Germany • Zerbst, Germany • Chihuahua City, Mexico • Bydgoszcz, Poland • Bytom, Poland • Nadarzyn, Poland • Nowa Sól, Poland • Poznan, Poland • Warsaw, Poland

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