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Terminated

Protocol was cancelled by company based on overall efficacy, no safety concern

An Efficacy and Safety Study of Golimumab in Participants With Ulcerative Colitis

ClinicalTrials.gov ID NCT00488774

Sponsor Janssen Research & Development, LLC

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

Last Update Posted 2013-06-14

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Study Overview

Brief Summary

The purpose of this study is to assess the effects (good and bad) of golimumab (CNTO 148) therapy in participants with active ulcerative colitis (UC) (sores in the colon).

Detailed Description

This is a randomized (study medication assigned by chance), double-blind (neither the Physician nor the participant know about the study medication), 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), parallel-group (a medical research study comparing the response in 2 or more groups of participants receiving different interventions [treatments]) study to evaluate an appropriate intravenous (through a vein in the arm) golimumab induction dose and to demonstrate the safety and efficacy of intravenous induction dosing with golimumab in participants with moderately to severely active UC. At Week 6, participants will be asked to participate in an additional 1-

Study Start
2007-08

Primary Completion (Actual)
2009-05

Study Completion (Actual)
2009-05

Enrollment (Actual)
291

Study Type
Interventional

Phase
Phase 2

Janssen Biotech, Inc.
Exhibit 2058
Accord v. Janssen
IPR2026-00259
Ex. 2058-001

to test if the drug has a real effect), parallel-group (a medical research study comparing the response in 2 or more groups of participants receiving different interventions [treatments]) study to evaluate an appropriate intravenous (through a vein in the arm) golimumab induction dose and to demonstrate the safety and efficacy of intravenous induction dosing with golimumab in participants with moderately to severely active UC. At Week 6, participants will be asked to participate in an additional 1-year maintenance study. Participants not entering the 1-year golimumab maintenance study will be evaluated for safety at Week 16. The duration of study will be 6 weeks for participants who enter the 1-year golimumab maintenance study and 16 weeks for participant who do not enter the 1-year golimumab maintenance study.There are 2 parts in this study. Part 1 is Phase 2 "dose-ranging" portion of study. Participants enrolled in Part 1, will receive a single intravenous infusion of either matching placebo for golimumab or 1 milligram (mg) per kilogram(kg), 2 mg per kg or 4 mg per kg of golimumab. Part 2 of the study is called "dose-confirming" and newly enrolled participants will receive same doses studied in Part 1, until the doses for Part 2 are selected and Phase 3 begins. At the time that the final doses are selected, all newly enrolled participants will receive 1 of the selected doses or matching placebo; this is the start of the Phase 3 portion of the study. Participants will primarily be assessed using Mayo Score (it is a score developed for measuring disease activity). Participants' safety and quality of life will also be monitored throughout the study.

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Study Type

Interventional

Phase

Phase 2
Phase 3

Official Title

A Phase 2/3 Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Safety and Efficacy of Golimumab Induction Therapy, Administered Intravenously, in Subjects With Moderately to Severely Active Ulcerative Colitis

Conditions

Colitis, Ulcerative

Intervention / Treatment

- Other: Placebo
- Drug: Golimumab 1 mg per kg
- Drug: Golimumab 2 mg per kg
- Drug: Golimumab 4 mg per kg

Other Study ID Numbers

- CR014188
- C0524T16 (Other Identifier) (OTHER: Janssen Research & Development, LLC)
- 2006-003397-94 (Other Identifier) (OTHER: Janssen Research & Development, LLC)

Obsolete Identifiers

- NCT01842152

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Resource links provided by the National Library of Medicine

NIH NLM

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- NCT01842152

Resource links provided by the National Library of Medicine

NIH NLM

MedlinePlus related topics: Ulcerative Colitis

Drug Information available for: Golimumab

FDA Drug and Device Resources

Glossary

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the Contacts and Locations section in How to Read a Study Record.

This study has 108 locations

United States

California Locations
- Orange, California, United States
- Roseville, California, United States

Colorado Locations
- Littleton, Colorado, United States

Connecticut Locations
- Bristol, Connecticut, United States

Florida Locations
- Tampa, Florida, United States

Iowa Locations
- Fort Dodge, Iowa, United States

Kansas Locations
- Topeka, Kansas, United States

Kentucky Locations
- Louisville, Kentucky, United States

Maryland Locations
- Laurel, Maryland, United States

Michigan Locations
- Dearborn, Michigan, United States
- Troy, Michigan, United States

Missouri Locations
- Mexico, Missouri, United States
- St Louis, Missouri, United States

New Hampshire Locations
- Lebanon, New Hampshire, United States

New York Locations
- Great Neck, New York, United States

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St Louis, Missouri, United States

New Hampshire Locations

Lebanon, New Hampshire, United States

New York Locations

Great Neck, New York, United States
Huntington, New York, United States
New York, New York, United States

North Carolina Locations

Charlotte, North Carolina, United States
Kinston, North Carolina, United States

Ohio Locations

Cincinnati, Ohio, United States
Cleveland, Ohio, United States

Oklahoma Locations

Oklahoma City, Oklahoma, United States
Tulsa, Oklahoma, United States

Pennsylvania Locations

Philadelphia, Pennsylvania, United States

South Carolina Locations

Charleston, South Carolina, United States
Columbia, South Carolina, United States

Tennessee Locations

Germantown, Tennessee, United States
Nashville, Tennessee, United States

Texas Locations

Austin, Texas, United States
Galveston, Texas, United States

Vermont Locations

Burlington, Vermont, United States

Virginia Locations

Christiansburg, Virginia, United States
Richmond, Virginia, United States

Washington Locations

Bellevue, Washington, United States

Wisconsin Locations

Madison, Wisconsin, United States
Milwaukee, Wisconsin, United States

Australia

Adelaide, Australia
Brisbane, Australia
Malvern, Australia

Austria

Innsbruck, Austria

Belgium

Bonheiden, Belgium
Leuven, Belgium

Bulgaria

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This study has 108 locations

Belgium

- Bonheiden, Belgium
- Leuven, Belgium

Bulgaria

- Rousse, Bulgaria
- Varna, Bulgaria

Canada

Alberta Locations

- Calgary, Alberta, Canada

British Columbia Locations

- Vancouver, British Columbia, Canada
- Victoria, British Columbia, Canada

Ontario Locations

- Hamilton, Ontario, Canada
- Kingston, Ontario, Canada
- London, Ontario, Canada

Quebec Locations

- Montreal, Quebec, Canada

Saskatchewan Locations

- Saskatoon, Saskatchewan, Canada

France

- Clichy, France
- Lille, France
- Nice, France

Germany

- Herne, Germany
- Magdeburg, Germany

Free and Hanseatic City of Hamburg Locations

- Hamburg, Free and Hanseatic City of Hamburg, Germany

State of Berlin Locations

- Berlin, State of Berlin, Germany

Hungary

- Békéscsaba, Hungary
- Budapest, Hungary
- Győr, Hungary
- Gyulai Ut 18, Hungary
- Miskolc, Hungary
- Pécs, Hungary
- Székesfehérvár, Hungary
- Szombathely, Hungary

India

- Hyderabad Andh Prad, India
- Jaipur, India
- Lucknow, India
- Ludhiana, India
- Pune, India

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This study has 108 locations

- Hyderabad Andh Prad, India
- Jaipur, India
- Lucknow, India
- Ludhiana, India
- Pune, India

Israel

- Afula, Israel
- Hedera, Israel
- Jerusalem, Israel
- Kfar Saba, Israel
- Tel Aviv, Israel

Latvia

- Daugavpils, Latvia
- Riga, Latvia

Lithuania

- Klaipėda, Lithuania
- Šiauliai, Lithuania
- Vilnius LT, Lithuania

Netherlands

- Amsterdam, Netherlands
- Groningen, Netherlands
- Leiden, Netherlands
- Rotterdam, Netherlands

New Zealand

- Auckland, New Zealand
- Hastings, New Zealand

Poland

- Bialystok, Poland
- Częstochowa, Poland
- Krakow, Poland
- Lodz, Poland
- Skierniewice, Poland
- Sopot, Poland

Romania

- Bucharest, Romania
- Timișoara, Romania

Russia

- Moscow, Russia
- Saint Petersburg, Russia
- Yaroslavl, Russia

Serbia

- Belgrade, Serbia

Slovakia

- Bratislava, Slovakia

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This study has 108 locations

Serbia

- Belgrade, Serbia

Slovakia

- Bratislava, Slovakia
- Nitra, Slovakia
- Prešov, Slovakia

Sweden

- Gothenburg, Sweden

Ukraine

- Donetsk, Ukraine
- Ivano, Ukraine
- Kiev, Ukraine
- Vynnytsya, Ukraine

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Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies.

Eligibility Criteria

Description

Inclusion Criteria:

- Participants diagnosed with moderately to severely active ulcerative colitis (UC) defined by a Mayo score of 6 to 12 inclusive at Baseline (Week 0), including an endoscopic (examination of an internal part of the body with a lighted tube; looking at a part of the body with a lighted tube) subscore of greater than or equal to 2
- Participants must have biopsy results (collected at the screening endoscopy (procedure or obtained within the last year) consistent with the diagnosis of UC
- Participants either currently receiving treatment with, or have a history of failure to respond to, or tolerate, at least 1 of the following therapies: oral 5-aminosalicylate (5-ASAs), oral corticosteroids, 6-mercaptopurine (6-MP) and azathioprine (AZA)
- Participants with current dependency or with a history of corticosteroid dependency (i.e. an inability to successfully taper corticosteroids without a return of the symptoms of UC) - Not have a diagnosis of active TB

Exclusion Criteria:

- Participants with previous exposure to biologic anti-tumor necrosis factor (TNF) agents

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

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corticosteroid dependency (i.e. an inability to successfully taper corticosteroids without a return of the symptoms of UC) - Not have a diagnosis of active TB

Exclusion Criteria:

- Participants with previous exposure to biologic anti-tumor necrosis factor (TNF) agents
- Participants with severe extensive UC that is likely to require a colectomy (surgery to remove part or all of the colon) within 12 weeks of study entry
- Participants having UC limited to the rectum only or to less than 20 centimeter (cm) of the colon
- Presence of a stoma (an artificial permanent opening especially in the abdominal wall made in surgical procedures) or presence of a fistula
- Participants with a history of extensive colonic resection

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Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

Expand all / Collapse all

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Placebo Comparator: Placebo Matching placebo for golimumab, intravenous (IV) (through a vein in the arm) infusion administered at Week 0	Other: Placebo • Matching placebo for golimumab, intravenous infusion administered at Week 0
Experimental: Golimumab 1 milligram (mg) per kilogram (kg) Golimumab 1 mg per kg intravenous (IV) infusion administered at Week 0.	Drug: Golimumab 1 mg per kg • Golimumab 1 mg per kg intravenous (IV) infusion administered at Week 0 • Other Names: ◦ CNTO 148

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Experimental: Golimumab 1 milligram (mg) per kilogram (kg) Golimumab 1 mg per kg intravenous (IV) infusion administered at Week 0.	Drug: Golimumab 1 mg per kg • Golimumab 1 mg per kg intravenous (IV) infusion administered at Week 0 • Other Names: ◦ CNTO 148
Experimental: Golimumab 2 mg per kg Golimumab 2 mg per kg intravenous (IV) infusion administered at Week 0.	Drug: Golimumab 2 mg per kg • Golimumab 2 mg per kg intravenous (IV) infusion administered at Week 0 • Other Names: ◦ CNTO 148
Experimental: Golimumab 4 mg per kg Golimumab 4 mg per kg, intravenous (IV) infusion administered at Week 0.	Drug: Golimumab 4 mg per kg • Golimumab 4 mg per kg intravenous (IV) infusion at Week 0

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With Clinical Response	Clinical response is defined as decrease from baseline in Mayo score by greater than or equal to 30 percent and greater than or equal to 3, with either a decrease from baseline in rectal bleeding sub-score of greater than or equal to 1 or a rectal bleeding sub-score of 0 or 1. The Mayo score is sum of 4 sub-scores (i.e., stool frequency, rectal bleeding, endoscopic findings, and a physician's global assessment); each rated on a scale from 0 to 3, with higher scores indicating more severe disease. The total Mayo score value ranges from 0 to 12.	Week 6

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With Clinical Remission	Clinical remission is defined as a Mayo score of less than or equal to 2, with no individual sub-score greater than 1. The Mayo score is sum of 4 sub-scores (i.e., stool frequency, rectal bleeding, endoscopic findings, and a physician's global assessment); each rated on a scale from 0 to 3, with higher scores indicating more severe disease. The total Mayo score value ranges from 0 to 12.	Week 6

Participants With Clinical Remission	equal to 2, with no individual sub-score greater than 1. The Mayo score is sum of 4 sub-scores (i.e., stool frequency, rectal bleeding, endoscopic findings, and a physician's global assessment); each rated on a scale from 0 to 3, with higher scores indicating more severe disease. The total Mayo score value ranges from 0 to 12.	

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Janssen Research & Development, LLC

Collaborators

- Merck Sharp & Dohme LLC

Investigators

- Study Director: Janssen Research & Development, LLC Clinical Trial, Janssen Research & Development, LLC

Publications

From PubMed

These publications are automatically filled in from PubMed, a public database of scientific and medical articles, and may or may not be about the study.

- Adedokun OJ, Xu Z, Liao S, Strauss R, Reinisch W, Feagan BG, Sandborn WJ. Population Pharmacokinetics and Exposure-Response Modeling of Golimumab in Adults With Moderately to Severely Active Ulcerative Colitis. Clin Ther. 2020 Jan;42(1):157-174.e4. doi: 10.1016/j.clinthera.2019.11.010. Epub 2020 Jan 22.
- Rutgeerts P, Feagan BG, Marano CW, Padgett L, Strauss R, Johanns J, Adedokun OJ, Guzzo C, Zhang H, Colombel JF, Reinisch W, Gibson PR, Sandborn WJ; PURSUIT-IV study group. Randomised clinical trial: a placebo-controlled study of intravenous golimumab induction therapy for ulcerative colitis. Aliment Pharmacol Ther. 2015 Sep;42(5):504-14. doi: 10.1111/apt.13291. Epub 2015 Jun 29.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates	Results Reporting Dates
First Submitted	**Results First Submitted**
2007-06-18	2013-04-29
First Submitted that Met QC Criteria	**Results First Submitted that Met QC Criteria**
2007-06-18	2013-04-29
First Posted (Estimated)	**Results First Posted (Estimated)**

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Study Registration Dates	
First Submitted	2007-06-18
First Submitted that Met QC Criteria	2007-06-18
First Posted (Estimated)	2007-06-20

Results Reporting Dates	
Results First Submitted	2013-04-29
Results First Submitted that Met QC Criteria	2013-04-29
Results First Posted (Estimated)	2013-06-14

Certification/Extension Dates	
Certification/Extension First Submitted	2009-12-03
Certification/Extension First Submitted that Met QC Criteria	2009-12-03
Certification/Extension First Posted (Estimated)	2010-03-04

Study Record Updates	
Last Update Submitted that Met QC Criteria	2013-04-29
Last Update Posted (Estimated)	2013-06-14
Last Verified	2013-04

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Record History

Expand all / Collapse all

Terms related to this study

Keywords Provided by Janssen Research & Development, LLC

Colitis, ulcerative
Golimumab
CNTO 148

Additional Relevant MeSH Terms

Colitis
Gastroenteritis
Gastrointestinal Diseases
Digestive System Diseases
Inflammatory Bowel Diseases
Colonic Diseases
Intestinal Diseases
Colitis, Ulcerative
golimumab

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2009-12-03

Certification/Extension First Submitted that Met QC Criteria

2009-12-03

Certification/Extension First Posted (Estimated)

2010-03-04

2013-04-29

Last Update Posted (Estimated)

2013-06-14

Last Verified

2013-04

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Expand all / Collapse all

Terms related to this study

Keywords Provided by Janssen Research & Development, LLC

Colitis, ulcerative
Golimumab
CNTO 148

Additional Relevant MeSH Terms

Colitis
Gastroenteritis
Gastrointestinal Diseases
Digestive System Diseases
Inflammatory Bowel Diseases
Colonic Diseases
Intestinal Diseases
Colitis, Ulcerative
golimumab

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National Library of Medicine
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Revision: v3.5.5

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