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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) ⓘ

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Study Type ⓘ

Interventional

Phase ⓘ

Phase 2

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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.

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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Study Type

Interventional

Phase

Phase 2

Phase 3

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Resource links provided by the National Library of Medicine

[MedlinePlus](#) related topics: [Ulcerative Colitis](#)[Drug Information](#) available for: [Golimumab](#)[FDA Drug and Device Resources](#)

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



- This study has 108 locations
- [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**



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



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



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[Click to view interactive map](#)**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

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

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

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, Johans 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

First Submitted ⓘ

2007-06-18

First Submitted that Met QC Criteria ⓘ

2007-06-18

First Posted (Estimated) ⓘ

Results Reporting Dates

Results First Submitted ⓘ

2013-04-29

Results First Submitted that Met QC Criteria ⓘ

2013-04-29

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

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

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

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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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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Golimumab

CNT0 148

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Gastrointestinal Diseases

Digestive System Diseases

Inflammatory Bowel Diseases

Colonic Diseases

Intestinal Diseases

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