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Phase 2b efficacy and safety study of JNJ-77242113 in participants with ulcerative colitis

Submission date
19/08/2023

Recruitment status
No longer recruiting

Registration date
13/11/2023

Overall study status
Completed

Last Edited
26/10/2026

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Ulcerative colitis (UC) is a chronic disease of the large intestine (colon) in which the lining of the colon becomes inflamed and develops tiny open sores (ulcers).
JNJ-77242113 is an oral medicine that is designed to bind to IL-23 receptor and block IL-23* activity.
*IL-23 is a type of protein involved in inflammation.
The aim of this study is to learn about the effectiveness and safety of JNJ-77242113 for treatment of ulcerative colitis compared to placebo (any treatment that has no active properties).
Safety assessments may include physical examination, vital signs, electrocardiograms, laboratory assessments and adverse event.
Efficacy assessment will include UC disease evaluation (Mayo score histology, C-reactive protein, fecal calprotectin [a measure of inflammation in stool]) and patient-reported outcomes.

Who can participate?
This study will include participants aged 18 years and older with moderate to severe UC.

What does the study involve?
The study will include:
1. Screening period (up to 6 weeks)
2. Main treatment period (28 weeks) divided into 4 groups:
• Group 1: JNJ-77242113 Dose-1:
Participants will receive JNJ-77242113 Dose-1 tablets orally from Week 0 through Week 28.
• Group 2: JNJ-77242113 Dose-2:
Participants will receive JNJ-77242113 Dose-2 tablets orally from Week 0 through Week 28.
• Group 3: JNJ-77242113 Dose-3:
Participants will receive JNJ-77242113 Dose-3 tablets orally from Week 0 through Week 28.
• Group 4: Placebo:
Participants will receive placebo tablets orally from Week 0 through Week 28. Participants who receive placebo and experience an inadequate response will be switched to receive JNJ-77242113 Dose-3 tablets from Week 16 through Week 28.
3. Long term extension (LTE) period (48 weeks):

Participants who complete Week 28 assessment and are responding to treatment will continue the same treatment until Week 76 in LTE period.
4. Safety follow-up period (2 weeks after the last dose of study intervention)
Overall duration of study will be up to 84 weeks.

What are the possible benefits and risks of participating?
There is no established benefit to participants of this study. Based on scientific theory, taking JNJ-77242113 may improve UC. However, this cannot be guaranteed because JNJ-77242113 is still under investigation as a treatment and it is not known whether JNJ-77242113 will work. Participants may experience some benefit from participation in the study that is not due to receiving study drug, but due to regular visits and assessments monitoring overall health. Participation may help other people with UC in the future.
Participants may have side effects from the drugs or procedures used in this study that may be mild to severe and even life-threatening, and they can vary from person to person. Potential risks include worsening of UC, hypersensitivity reaction, immunogenicity, infection after getting the study drug or placebo. Risk due to study procedure is risks associated with video endoscopy (flexible sigmoidoscopy/full colonoscopy) including bleeding, post procedure discomfort or intestinal perforation.
The participant information sheet and informed consent form, which will be signed by every participant agreeing to participate in the study, includes a detailed section outlining the known risks to participating in the study.
Not all possible side effects and risks related to JNJ-77242113 are known at this moment. During the study, the sponsor may learn new information about JNJ-77242113. The study doctor will tell participants as soon as possible about any new information that might make them change their mind about being in the study, such as new risks.
To minimize the risk associated with taking part in the study, participants are frequently assessed for any side effects and other medical events. Participants are educated to report any such events to the study doctor who will provide appropriate medical care.
Any serious side effects that are reported to the sponsor are thoroughly reviewed by a specialist drug safety team.
There are no costs to participants to be in the study. The sponsor will pay for the study drug and tests that are part of the study. The participant will receive reasonable reimbursement for study-related costs (e.g., travel/parking costs).

Where is the study run from?
Janssen-Cilag International NV (Netherlands)

When is the study starting and how long is it expected to run for?
August 2023 to January 2026

Who is funding the study?
Janssen Research and Development (Netherlands)

Who is the main contact?
Jonathan Chapman, JanssenUKRegistryQueries@its.jnj.com

Contact information

Type(s)
Scientific

Contact name
None Medical Information and Product Information Enquiry

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06049017

Clinical Trials Information System (CTIS)
2023-504673-20

Integrated Research Application System (IRAS)
1008443

Central Portfolio Management System (CPMS)
57128

Protocol serial number
77242113UCO2001

Study information

Scientific Title
A phase 2b multicenter, randomized, placebo-controlled, dose-ranging study to evaluate the efficacy and safety of JNJ-77242113 for the treatment of moderately to severely active ulcerative colitis

Acronym

ANTHEM-UC

Study objectives
Primary objectives:
To evaluate the efficacy of JNJ-77242113 versus placebo in inducing clinical response

Secondary objectives:
1. To evaluate the efficacy of JNJ-77242113 versus placebo in inducing a range of outcomes
2. To evaluate the safety of JNJ-77242113 versus placebo

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/11/2023, South Central - Berkshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048276; berkshireb.rec@hra.nhs.uk), ref: 23/SC/0306

Primary study design
Interventional

Study design
Interventional double-blind randomized parallel-group placebo-controlled crossover trial

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Ulcerative colitis

Interventions
The study will include:
1. Screening period (up to 6 weeks)
2. Main treatment period (28 weeks) divided into 4 groups:

Group 1: JNJ-77242113 Dose-1:
Participants will receive JNJ-77242113 Dose-1 tablets orally from Week 0 through Week 28.

Group 2: JNJ-77242113 Dose-2:
Participants will receive JNJ-77242113 Dose-2 tablets orally from Week 0 through Week 28.

Group 3: JNJ-77242113 Dose-3:
Participants will receive JNJ-77242113 Dose-3 tablets orally from Week 0 through Week 28.

Group 4: Placebo:
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3. Long-term extension (LTE) period (48 weeks):
Participants who complete Week 28 assessment and are responding to treatment will continue the same treatment until Week 76 in LTE period.

4. Safety follow-up period (2 weeks after the last dose of study intervention)

Overall duration of study will be up to 84 weeks.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
JNJ-77242113

Primary outcome(s)
Efficacy assessment will include UC disease evaluation (Mayo score histology, C-reactive protein, fecal calprotectin [a measure of inflammation in stool]) and patient reported outcomes. Measured at week 0, week 12 and week 28 of the main phase, and week 76 of the Long term extension phase.

Key secondary outcome(s)
UC disease evaluation (Mayo score histology, C-reactive protein, fecal calprotectin [a measure of inflammation in stool]) and patient reported outcomes to assess:
1. Clinical remission at Week 12
2. Symptomatic remission at Week 12
3. Endoscopic improvement at Week 12
4. Histologic-endoscopic mucosal improvement at Week 12
5. Frequency and type of AEs and SAEs

Completion date
05/01/2026

Eligibility

Key inclusion criteria
1. 18 years (or the legal age of consent in the jurisdiction in which the study is taking place) or older.
2. Documented diagnosis of UC of at least 12 weeks prior to screening, with colitis confirmed at any time in the past by radiography, histology, and/or endoscopy.
3. Moderately to severely active UC, defined as baseline (Week 0) modified Mayo score of 5 to 9, inclusive, using the endoscopy subscore obtained during the central review of the screening video endoscopy.
4. An endoscopy subscore ≥2 as obtained during central review of the screening video endoscopy.
5. A participant who had extensive UC for ≥8 years, or disease limited to the left side of the colon for ≥10 years, must:
5.1. have had a complete colonoscopy, to assess for the presence of dysplasia within 1 year before the first dose of study intervention.

OR
5.2. have a complete colonoscopy with biopsy surveillance for dysplasia at the time of baseline endoscopy performed during the screening period.
6. A participant ≥45 years of age must either have had a full colonoscopy to assess for the presence of adenomatous polyps within 5 years before the first dose of study intervention or a complete colonoscopy to assess for the presence of adenomatous polyps at the screening visit. The adenomatous polyps must be removed before the first dose of study intervention.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
252

Key exclusion criteria
1. Patients with current or prior diagnosis of fulminant colitis and/or toxic megacolon.
2. UC limited to rectum only or to <15 cm of colon.
3. Presence of a stoma.
4. Presence or history of fistula.
5. Has required or will require surgery for active GI bleeding, peritonitis, intestinal obstruction, or intra-abdominal abscess requiring surgical drainage, or other conditions possibly confounding the evaluation of benefit from study intervention treatment within the 8 weeks prior to screening.
6. History of extensive colonic resection (eg, < 30 cm of colon remaining).
7. History of colonic mucosal dysplasia. Participants will not be excluded from the study because of pathology finding of “indefinite for dysplasia with reactive atypia.”
8. Has a stool culture or other examination positive for an enteric pathogen, including Clostridioides difficile (formerly known as Clostridium difficile) toxin, within 4 months before the first dose of study intervention, unless a repeat examination is negative and there are no signs of ongoing infection with that pathogen. Note: Treatment and repeat testing can occur in the current screening period.
9.. Has a history of severe, progressive, or uncontrolled renal, genitourinary, hepatic, biliary, hematologic, endocrine, cardiac, vascular, pulmonary, rheumatologic, neurologic, psychiatric, or metabolic disturbances, or signs and symptoms thereof.

Date of first enrolment

09/10/2023

Date of final enrolment
19/07/2024

Locations

Countries of recruitment
United Kingdom

Argentina

Australia

Belgium

Brazil

Canada

China

France

Germany

Hungary

India

Italy

Japan

Malaysia

Mexico

Poland

Romania

Spain

Türkiye

Study participating centre
St George's University Hospitals NHS Foundation Trust
Blackshaw Rd
London

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SW17 0QT

Study participating centre
Northern Care Alliance NHS Foundation Trust
Fairfield General Hospital
Rochdale Old Road
Bury
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BL9 7TD

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
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OX3 9DU

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Great Maze Pond
London
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SE1 9RT

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Hills Road
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CB2 0QQ

Study participating centre
Kings College Hospital NHS Foundation Trust
Kings College Hospital
Denmark Hill
London
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SE5 9RS

Study participating centre
St Helens and Knowsley Teaching Hospitals NHS Trust
Warrington Rd
Rainhill
Prescot
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L35 5DR

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
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Study participating centre
Barts Health NHS Trust
Whipps Cross Hospital
Whipps Cross Road
Leytonstone
England
E11 1NR

Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type
Industry

Funder Name
Janssen Research and Development

Alternative Name(s)
Janssen R&D, Janssen Research & Development, Janssen Research & Development, LLC, Janssen Research & Development LLC, Janssen Pharmaceutical Companies of Johnson & Johnson, Research & Development at Janssen, JRD, J&J PRD

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing policy of the Janssen Pharmaceutical Companies of Johnson & Johnson is available at www.janssen.com/clinicaltrials/ transparency. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at yoda.yale.edu

IPD sharing plan summary
Available on request