

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

<b>Submission date</b> 19/08/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/11/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/03/2025	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 November 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

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**Type(s)**

Principal investigator

**Contact name**

Prof Jimmy Limdi

**Contact details**

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BL9 7TD  
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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**

2023-504673-20

**Integrated Research Application System (IRAS)**

1008443

**ClinicalTrials.gov (NCT)**

NCT06049017

**Protocol serial number**

77242113UCO2001, IRAS 1008443, CPMS 57128

## **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

**Study design**

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

**Primary study design**

Interventional

**Study type(s)**

Safety, Efficacy

**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:

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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**

30/11/2026

# **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  $\geq 2$  as obtained during central review of the screening video endoscopy.
5. A participant who had extensive UC for  $\geq 8$  years, or disease limited to the left side of the colon for  $\geq 10$  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  $\geq 45$  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**

Adult

**Lower age limit**

18 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

United Kingdom

SW17 0QT

**Study participating centre**

**Northern Care Alliance NHS Foundation Trust**  
Fairfield General Hospital  
Rochdale Old Road  
Bury  
United Kingdom  
BL9 7TD

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

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

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

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

**Study participating centre**  
**St Helens and Knowsley Teaching Hospitals NHS Trust**  
Warrington Rd



Rainhill  
Prescot  
United Kingdom  
L35 5DR

**Study participating centre**

**University Hospital Southampton NHS Foundation Trust**

Southampton General Hospital

Tremona Road

Southampton

United Kingdom

SO16 6YD

**Study participating centre**

**Barts Health NHS Trust**

Whipps Cross Hospital

Whipps Cross Road

Leytonstone

United Kingdom

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](http://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](http://yoda.yale.edu)

**IPD sharing plan summary**

Available on request