ISRCTN14103793 https://doi.org/10.1186/ISRCTN14103793

A study of JNJ-78934804 in participants with moderately to severely active Crohn's disease

Submission date 19/06/2026	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 21/08/2026	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 26/10/2026	**Condition category** Digestive System	[ ] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Crohn’s disease (CD) is a disease of the digestive system that causes inflammation and ulcers in the intestine (gut). Although targeted therapies have improved the treatment for CD, many participants do not respond or eventually stop responding to a single therapy, specifically after trying multiple treatments. Hence, new approaches like combining advanced therapies may help improve the outcomes.

JNJ-78934804 is a fixed-dose combination* of guselkumab & golimumab. Guselkumab binds to interleukin-23 (IL-23)* and golilumab binds to tumor necrosis factor alpha (TNFα)**. Blocking their effects helps to reduce the inflammation that occurs in CD.

*single product containing two drugs in a fixed amount

**specific type of proteins involved in inflammation

In this study, researchers want to assess how well JNJ-78934804 works when compared to guselkumab in participants with CD at Week 48.

Who can participate?

Participants aged 18 years or older with moderately to severely active CD

What does the study involve?

1. Screening period (up to 6 weeks)
2. Double-blind treatment period (up to 48 weeks): Participants will be randomly (by chance) divided into the following:

JNJ-78934804 group: Participants will receive JNJ-78934804 induction dose under the skin at Weeks 0, 4 and 8, followed by maintenance dose once every 4 weeks (q4w) from Week 12

Guselkumab group: Participants will receive guselkumab induction dose under the skin at Week 0, 4 and 8, followed by a guselkumab maintenance dose q4w from Week 12

Participants who meet the rescue criteria will receive a JNJ-78934804 induction dose at Weeks 16, 20, and 24, followed by a JNJ-78934804 maintenance dose q4w from Week 28

3. Long-term extension period (up to Week 144)
4. Safety follow-up period (up to 12 weeks after last dose of study intervention)

What are the possible benefits and risks of participating?

Safety assessments will include monitoring of adverse events, vital signs, screening

electrocardiogram (test to record heart activity), clinical laboratory, and pregnancy testing. The overall duration of the study will be around 3 years.
There is no established benefit to participants of this study. Based on scientific theory, taking JNJ-78934804 may improve CD. However, this cannot be guaranteed because JNJ-78934804 is still under investigation as a treatment and it is not known whether JNJ-78934804 will work.
In addition, if participants are put into the guselkumab treatment group, they may not receive JNJ-78934804 and may only receive guselkumab during this study unless specified.
Participants may experience some benefit from participation in the study that is not due to receiving the study drug but due to regular visits and assessments monitoring overall health.
Participation may help other people with CD 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 serious infections and reactivation of latent infections; hypersensitivity (exaggerated immune response) reactions; malignancy (presence of cancerous cells that grow in an uncontrolled manner); congestive heart failure (heart condition in which ventricles are too weak or stiff to pump efficiently); demyelinating disorders (conditions that damage the protective myelin sheath surrounding nerve fibres); lupus-like syndrome (triggered by prolonged use of specific medications like TNFα inhibitors); liver injury; and haematologic reactions (immune or non-immune responses to blood products). Risks due to study procedure include video ileocolonoscopy (a complete colonoscopy, a procedure for examining parts of the intestine and colon using a tube called a colonoscope), including bleeding, post-procedure discomfort or intestinal perforation (the formation of holes in the intestine) after the procedure. There are other, less frequent risks. 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-78934804 are known at this moment. During the study, the sponsor may learn new information about JNJ-78934804. 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 minimise the risk associated with taking part in the study, participants are frequently reviewed for any side effects and other medical events. Participants are educated to report any such events to their 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

When is the study starting and how long is it expected to run for?
May 2026 to July 2030

Who is funding the study?
Janssen Research and Development

Who is the main contact?
medinfo@its.jnj.com

Contact information

Type(s)
Scientific, Public

Contact name
None Janssen UK Registry

Contact details
Janssen Research & Development (Janssen-Cilag Ltd), 20 Grenfell Road
Maidenhead
United Kingdom
SL6 1EH
-
JanssenUKRegistryQueries@its.jnj.com

Type(s)
Principal investigator

Contact name
Dr Daniel Gaya

Contact details
Glasgow Royal Infirmary
Glasgow
United Kingdom
G4 0SF

Additional identifiers

Clinical Trials Information System (CTIS)
2026-525922-39

Integrated Research Application System (IRAS)
1013941

Central Portfolio Management System (CPMS)
73306

Sponsor's protocol code number
78934804CRD3001

Study information

Scientific Title
A Phase III, randomized, double-blind, and active-controlled multicenter study to evaluate the efficacy and safety of JNJ-78934804 in participants with moderately to severely active Crohn's disease

Acronym
DUET ENCORE-CD

Study objectives
Primary objectives:
To assess how well JNJ-78934804 works when compared to guselkumab at Week 48

Secondary objectives:
1. To assess how well JNJ-78934804 works when compared to guselkumab
2. To assess how safe JNJ-78934804 is compared to guselkumab

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/08/2026, Wales Research Ethics Committee 5 (Health and Care Research Wales, Floor 4, Crown Building, Cardiff, CF10 3NQ, United Kingdom; -; Wales.REC5@wales.nhs.uk), ref: 26/WA/0190

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Single

Purpose
Safety

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Crohn’s disease

Interventions
Screening period (up to 6 weeks) and double-blind treatment period (up to 48 weeks). Participants will be randomly (by chance) divided into the following groups:

Experimental: JNJ-78934804
Participants will receive a JNJ-78934804 induction dose at weeks 0, 4, and 8, followed by a JNJ-78934804 maintenance dose once every 4 weeks (q4w) starting at week 12. All participants who meet the rescue criteria will receive a JNJ-78934804 induction dose at weeks 16, 20, and 24, followed by a JNJ-78934804 maintenance dose q4w starting at week 28. Participants who complete the double-blind treatment phase (Week 48) and who may benefit from continued

study intervention in the opinion of the investigator will have the opportunity to enter the long-term extension (LTE) phase.

Active Comparator: Guselkumab
Participants will receive a guselkumab induction dose at weeks 0, 4, and 8, followed by a guselkumab maintenance dose q4w starting at week 12. All participants who meet the rescue criteria will receive a JNJ-78934804 induction dose at weeks 16, 20, and 24, followed by a JNJ-78934804 maintenance dose q4w starting at week 28. Participants who complete the double-blind treatment phase (Week 48) and who may benefit from continued study intervention in the opinion of the investigator will have the opportunity to enter the LTE phase.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Guselkumab, JNJ-78934804 (guselkumab and golimumab)

Primary outcome(s)
1. Co-primary outcome: Percentage of participants with clinical remission at week 48. Clinical remission is defined as a Crohn's Disease Activity Index (CDAI) score <150.
2. Co-primary outcome: Percentage of participants with endoscopic remission at week 48. Endoscopic remission is defined as a Simple Endoscopic Score for Crohn's Disease (SES-CD) score of <=4 with at least a 2-point reduction from baseline and no subscore greater than (>) 1 in any individual component.

Key secondary outcome(s)
1. Percentage of participants with deep remission at week 48. Deep remission (composite endpoint) is defined as achieving both clinical remission and endoscopic remission at Week 48 at the participant level. Clinical remission is defined as a CDAI score of <150 and endoscopic remission is defined as a SES-CD score of <=4 with at least a 2-point reduction from baseline and no subscore >1 in any individual component.
2. Percentage of Participants with corticosteroid-free (90-day) clinical remission at week 48. Corticosteroid-free (90-day) clinical remission at Week 48 is defined as clinical remission at Week 48 and not receiving corticosteroids for at least 90 days prior to Week 48. Clinical remission is defined as a CDAI score of <150.
3. Percentage of participants with corticosteroid-free (90-day) patient-reported outcome(s) (PRO-2) remission at week 48, defined as an abdominal pain (AP) mean daily score <=1 and stool frequency (SF) mean daily score <=2.8, no worsening of AP or SF from baseline, and not receiving corticosteroids for at least 90 days prior to Week 48.
4. Percentage of participants with sustained clinical remission, defined as clinical remission at Week 12 and Week 48. Clinical remission is defined as a CDAI score of <150. CDAI scores range from 0 to approximately 600.
5. Percentage of participants with histologic-endoscopic remission at week 48, defined as achieving a combination of histologic remission and endoscopic remission. Histologic remission is defined as absence of neutrophils from the mucosa (both lamina propria and epithelium), no crypt destruction, and no erosions, or ulcerations or granulation tissue as assessed by the Robarts Histopathology Index. Endoscopic remission is defined as a SES-CD score of <=4 with at least a 2-point reduction from baseline and no subscore > 1 in any individual component.

6. Percentage of participants with Inflammatory Bowel Disease Questionnaire (IBDQ) responses at week 48. IBDQ response at Week 48 is defined as an improvement of at least 16 points in the IBDQ total score from baseline at Week 48.
7. Percentage of participants with Patient-Reported Outcomes Measurement Information System 29 (PROMIS-29) Mental Component Summary Score (MCS) response at Week 48, defined as an improvement of at least 7 points in the PROMIS-29 MCS score from baseline at Week 48.
8. Percentage of participants with clinical remission at week 12. Clinical remission at week 12 is defined as a CDAI score of <150 at week 12.
9. Percentage of participants with endoscopic response at week 12, defined as >50% improvement from baseline in SES-CD score at week 12 or a decrease of at least 2 points in participants with a baseline score of 4 and isolated ileal disease.
10. Number of participants with adverse events (AE) and serious AEs (SAEs). An AE is any untoward medical occurrence in a clinical study participant administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. An SAE is any untoward medical occurrence that at any dose results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalisation; results in persistent or significant disability/incapacity; is a congenital anomaly /birth defect; is a suspected transmission of any infectious agent via a medicinal product; and is medically important.

Completion date
12/07/2030

Eligibility

Key inclusion criteria
1. At the time of informed consent, must be ≥18 years of age
2. Have a diagnosis of Crohn's disease (CD) or fistulizing CD established >=12 weeks before screening including both endoscopic evidence and a histopathology report consistent with a diagnosis of CD
3. Have moderately to severely active CD based on Crohn’s Disease Activity Index (CDAI) criteria defined as a baseline CDAI >=220 but <=450 and either
3.1. Mean daily stool frequency (SF) count >= 4.0, based on the unweighted CDAI component of the number of liquid or very soft stools, or
3.2. Mean daily AP score >=2.0, based on the unweighted CDAI component of abdominal pain (AP)
4. Have moderately to severely active ileal and/or colonic CD as assessed by central review of the screening video ileocolonoscopy based on Simple Endoscopic Score for Crohn’s Disease (SES-CD) criteria
5. Have an inadequate initial response, loss of response, or intolerance to previously approved systemic therapies

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Diagnosis of indeterminate colitis, microscopic colitis, ischemic colitis, UC or clinical findings highly suggestive of UC or clinical findings highly suggestive of UC
2. Complications of CD such as symptomatic bowel strictures or stenoses, or any other manifestation that may require intestinal surgery while enrolled in the study.
3. Presence of draining (that is, functioning) stoma or ostomy
4. Has a history of short bowel syndrome, is missing >2 of the 5 ileocolonic segments, or has any other medical condition that could preclude or confound the ability to assess efficacy assessment tools (such as CDAI) to assess response to study intervention.
5. Currently has or is suspected of having an abscess

Date of first enrolment
28/05/2026

Date of final enrolment
12/07/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Argentina

Australia

Austria

Belgium

Brazil

Bulgaria

Canada

China

Czech Republic

Denmark

France

Germany

Greece

Hungary

India

Israel

Italy

Japan

Korea, South

Malaysia

Mexico

Netherlands

Norway

Poland

Portugal

Romania

Slovakia

Spain

Switzerland

Taiwan

United States of America

Study participating centre

Fairfield General Hospital
Rochdale Old Road
Bury
England
BL9 7TD

Study participating centre
Ulster Hospital
Upper Newtownards Rd
Dundonald
Belfast
Northern Ireland
BT16 1RH

Study participating centre
Kings College Hospital
Denmark Hill
London
England
SE5 9RS

Study participating centre
St George's Hospital
Blackshaw Road
Tooting
London
England
SW17 0QT

Study participating centre
Royal Devon & Exeter Foundation Hospital
Barrack Road
Exeter
England
EX2 5DW

Study participating centre
University Hospital Birmingham
Queen Elizabeth Hospital
Edgbaston
Birmingham

England
B15 2TH

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
Scotland
DD1 9SY

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
England
CF14 4XW

Study participating centre
Chelsea & Westminster Hospital
369 Fulham Road
London
England
SW10 9NH

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow
Scotland
G4 0SF

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
NE1 4LP

Study participating centre

John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type

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 Johnson & Johnson Innovative Medicine is available at https://www.innovativemedicine.jnj.com/our-innovation/clinical-trials/transparency. As noted on this site, requests for access to the study data can be submitted through the Yale Open Data Access (YODA) Project site at https://yoda.yale.edu.

IPD sharing plan summary

Available on request