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A study of guselkumab versus risankizumab in participants with moderately to severely active Crohn's Disease

Submission date 17/01/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/03/2026	**Overall study status** Ongoing	
Last Edited 10/04/2026	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Crohn's disease (CD) is a long-term, progressive (worsens with time) and life-threatening disease of the digestive system. Inflammation due to the disease penetrates the lining of digestive tract and may cause ulcers to form. Although guselkumab and risankizumab are approved treatments, still more information is needed to understand which treatment works better for patients with moderately to severely active CD who did not respond to other treatments.
Guselkumab and risankizumab are monoclonal antibodies* that blocks interleukin 23 (IL-23)**. Blocking the effects of IL-23 helps to reduce the inflammation that occurs in CD.
*A type of protein designed to recognise and attach to a specific target.
**A specific type of protein involved in inflammation.
In this study, researchers want to assess how well guselkumab works compared to risankizumab in patients with moderately to severely active CD.

Who can participate?
Participants aged 18 years or older with moderate to severely active CD who have previously failed
to respond to advanced therapies (ADT)*.
*New therapies to treat the disease.

What does the study involve?
The study consists of:
1. Screening period (up to 5 weeks)
2. Treatment period (up to Week 52): Participants will be randomly (by chance) assigned to either:
a. Guselkumab
b. Risankizumab
3. Post-intervention safety follow-up (up to 12 weeks after last dose of guselkumab or
16 weeks after last dose of risankizumab)

Safety assessments include clinical laboratory tests, physical examinations, vital signs, pregnancy testing, and tuberculosis screening. All side effects will be monitored until the end of study (up to Week 165).

What are the possible benefits and risks of participating?
There is no established benefit to participants of this study.
In addition, if participants are put into the risankizumab treatment group they may not receive guselkumab and may only receive risankizumab during this study unless specified.
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 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 hypersensitivity (exaggerated response by the immune system) reactions, increased risk of infections, tuberculosis, presence of malignancies (spread of cancer to other parts of body), immunizations (vaccinations), transaminase elevations (liver enzymes that release due to damage caused to liver or muscles) after getting the study drug or risankizumab. Risks due to Risankizumab include elevation in lipid parameters (increase in fat levels in the blood). Risks due to study procedure include exposure to radiation through radiographs (images produced due to radiation) and CT (computed tomography; procedure that uses a computer linked to an x-ray machine to make a series of detailed pictures of areas inside the body) scans and bleeding and colonic perforation(tear in the wall of large intestine) due to endoscopy procedures (procedure in which an instrument is introduced into the body to view its internal parts). 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 guselkumab are known at this moment. During the study, the sponsor may learn new information about guselkumab. 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 N.V.

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

Who is funding the study?
Janssen-Cilag International N.V.

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

Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2025-521590-13

Integrated Research Application System (IRAS)

1013251

Central Portfolio Management System (CPMS)
69953

Sponsor's protocol code number
CNTO1959CRD3009

Study information

Scientific Title
A phase 3b, multicenter, randomized, open-label, active-controlled study to compare the efficacy and safety of guselkumab versus risankizumab in the treatment of participants with moderately to severely active Crohn’s Disease

Acronym
CHARGE

Study objectives
Primary objective:
To assess how well guselkumab works compared to risankizumab at Week 52

Secondary objectives:
1. To further assess how well guselkumab works compared to risankizumab at Week 52
2. To assess how safe guselkumab is compared to risankizumab

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 17/01/2026, not yet known (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; a@a), ref: 26/WA/0033

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment, Safety

Study type(s)
Efficacy, Safety, Treatment, Other

Health condition(s) or problem(s) studied
Moderately to severely active Crohn's Disease

Interventions
Experimental: Guselkumab
Participants will receive guselkumab induction dose subcutaneously (SC) at Weeks 0, 4, and 8 followed by guselkumab maintenance dose SC once every 4 weeks (q4w) from Week 12 through Week 52.

Experimental: Risankizumab
Participants will receive risankizumab induction dose intravenously (IV) at Weeks 0, 4, and 8 followed by risankizumab maintenance dose SC once every 8 weeks (q8w) from Week 12 through Week 52.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Skyrizi 600mg concentrate for solution for infusion [Risankizumab] , Guselkumab [Guselkumab] , Skyrizi 360mg solution for injection in cartridge [Risankizumab]

Primary outcome(s)
Number of Participants with Deep Remission at Week 52 Deep remission is a composite endpoint defined as achieving both clinical remission and endoscopic remission at the participant level. Clinical remission is defined as Crohn’s Disease Activity Index (CDAI) score less than (<=) 4 with at least a 2-point reduction from baseline and no sub score greater than (>) 1 in any individual component and score can range from 0 to 56. Higher scores indicating severe disease.

Key secondary outcome(s))
1. Composite Endpoint of Number of Participants with Clinical Remission and Endoscopic Response at Week 52 Clinical remission is defined as CDAI score < 150-point. CDAI will be assessed by collecting information on 8 different CD-related variables: extra-intestinal manifestations, abdominal mass, weight, hematocrit, total number of liquid stools, abdominal pain/cramping, use of antidiarrheal drug(s), and/or opiates, and general well-being. In general, CDAI score ranges from 0 to approximately 600. Higher score indicates higher disease activity. Endoscopic response is defined as >50 percent (%) improvement from baseline in the SES CD or SES-CD score <= 2 or a decrease of at least 2 points in participants with a baseline score of 4 and isolated ileal disease. This is a composite endpoint defined to measure achievement of both clinical remission and endoscopic response. [Time Frame: At Week 52]
2. Number of Participants with Endoscopic Remission at Week 52 Endoscopic remission is defined as SES-CD <= 4 with at least a 2-point reduction from baseline and no sub score > 1 in any individual component and score can range from 0 to 56. Higher scores indicating severe disease. [Time Frame: At Week 52]

3. Number of Participants with Clinical Remission at Week 52 Clinical remission is defined as CDAI score < 150-point. CDAI will be assessed by collecting information on 8 different CD-related variables: extra-intestinal manifestations, abdominal mass, weight, hematocrit, total number of liquid stools, abdominal pain/cramping, use of antidiarrheal drug(s), and/or opiates, and general well-being. In general, CDAI score ranges from 0 to approximately 600. Higher score indicates higher disease activity. [Time Frame: At Week 52]
4. Number of Participants with Steroid-Free Clinical Remission at Week 52 Steroid-free clinical remission is defined as clinical remission at Week 52 and not receiving corticosteroids for at least 90 days prior to Week 52. Clinical remission is defined as CDAI score < 150-point. [Time Frame: At Week 52]
5. Number of Participants with Abnormalities in Laboratory Parameters Number of participants with abnormalities in laboratory parameters (hematology and chemistry) will be reported. [Time Frame: Up to Week 148]
6. Number of Participants With Change From Baseline in Laboratory Abnormalities Number of participants with change from baseline in laboratory abnormalities (hematology and chemistry) will be reported. [Time Frame: Up to week 148]
7. Number of Participants with Adverse Events (AEs), Serious AEs and AEs Leading to Discontinuation of Study Intervention An AE is any untoward medical occurrence in a participant administered a pharmaceutical (investigational or non investigational) product. An AE does not necessarily have a causal relationship with the treatment. An SAE is any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, 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. [Time Frame: Up to Week 165]

Completion date
11/12/2030

Eligibility

Key inclusion criteria
1. Has CD or fistulizing Crohn's Disease (CD) of at least 12 weeks' duration, with colitis, ileitis, or ileocolitis, confirmed at some time in the past by radiography, histology, and/or endoscopy
2. Have moderately to severely active CD, defined as baseline Crohn's Disease Activity Index (CDAI) score greater than or equal to (>=) 220 but less than or equal to (<=) 450
3. Baseline endoscopic evidence of active ileal and/or colonic CD as assessed by central endoscopy reading at the screening endoscopy defined as a screening Simple Endoscopic Score for Crohn's Disease (SES CD) >= 4 (for participants with isolated ileal disease) or >= 6 (for participants with colonic or ileocolonic disease), based on the presence of ulceration in any 1 of the 5 ileocolonic segments, resulting in the following specified ulceration component scores:
a. A minimum score of 1 for the component of "size of ulcers" AND
b. A minimum score of 1 for the component of "ulcerated surface"
4. In the opinion of the investigator, participant's disease is appropriate to treat with the maintenance dosing regimens utilized in the study
5. Adhere to the requirements for concomitant medications for the treatment of CD as mentioned in the protocol

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Has complications of CD such as symptomatic strictures or stenoses, short gut syndrome, active draining stoma or significant fistulizing disease or any other manifestation anticipated to require surgery within the next year, could preclude the use of the CDAI to assess response to therapy, or would possibly confound the ability to assess the effect of treatment with guselkumab or risankizumab
2. Currently has or is suspected to have an abscess
3. Has an active fistula during screening or at Week 0 with an anticipated need for surgery
4. Has had any kind of bowel resection within 24 weeks, or any other intraabdominal or other major surgery within 12 weeks, before first dose of study intervention
5. Currently has a malignancy or has a history of malignancy within 5 years before screening

Date of first enrolment
19/04/2026

Date of final enrolment
16/11/2027

Locations

Countries of recruitment
United Kingdom

Austria

Belgium

Canada

China

Czech Republic

Denmark

France

Germany

Hungary

Italy

Netherlands

Poland

Slovakia

Spain

Sweden

Study participating centre
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Study participating centre
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Sponsor information

Organisation

Janssen-Cilag International N.V.

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 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 Yale Open Data Access (YODA) Project site at yoda.yale.edu

IPD sharing plan summary
Stored in non-publicly available repository