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Switching to the IL-23 inhibitor guselkumab for people with active inflammatory bowel disease (IBD) who previously used ustekinumab (SHIFT-IBD)

Submission date
06/11/2025

Recruitment status
Recruiting

Registration date
07/11/2025

Overall study status
Ongoing

Last Edited
05/01/2026

Condition category
Digestive System

[X] 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
The SHIFT-IBD Study is looking at how well a medicine called guselkumab (also known by its brand name Tremfya) works for people with inflammatory bowel disease (IBD) who haven't had enough improvement with another medicine called ustekinumab. Researchers hope this study will help find better treatment options for people whose IBD is still active despite current therapies.

Who can participate?
Adults aged 18 and over who have had a confirmed diagnosis of IBD (Crohn's disease, ulcerative colitis, or IBD unclassified) for at least six months may be eligible. Participants must have been treated with ustekinumab for at least 14 weeks and either still be on it or have stopped it recently. They must also have ongoing signs of disease activity seen during a recent colonoscopy and be starting guselkumab based on their doctor's recommendation.

What does the study involve?
Participants will begin treatment with guselkumab as part of their regular care. Doctors can adjust the treatment as needed. The study will follow participants for one year, monitoring symptoms, test results, and overall health. The goal is to see how well guselkumab works and whether it helps control symptoms without worsening test results.

What are the possible benefits and risks of participating?
Participants may benefit from improved symptom control if guselkumab works better for them than previous treatments. As with any medication, there may be side effects or risks, but guselkumab will be given according to standard medical guidelines, and doctors will monitor participants closely.

Where is the study run from?
TIDHI Innovation Inc. (Canada)

When is the study starting and how long is it expected to run for?
The study began in September 2024 and is expected to run until December 2027.

Who is funding the study?
Janssen Canada.

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT07245394

Protocol serial number
TIDHI_001

Study information

Scientific Title
SHIFT-IBD: Switching to high-efficacy anti-IL-23 guselkumab in ustekinumab-exposed persons with active IBD

Acronym
SHIFT-IBD

Study objectives
The goal is to explore better treatment options for people whose IBD has not been well controlled with current therapies.
Researchers believe that switching to guselkumab may be as effective as other advanced treatments. For those who saw some improvement on ustekinumab but not enough, guselkumab may offer better symptom control—without worsening results on medical tests like endoscopy.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 07/11/2025, Advarra IRB (125 Don Hillock Drive, Unit 18, Aurora, ON, L4G 0H8, Canada; +1 905-727-7989; info@advarra.com), ref: Pro00090978

Study design
Multicenter prospective observational non-interventional single-arm cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Inflammatory Bowel Diseases (IBD)

Interventions
Guselkumab:
Induction: 200 mg IV or 400 mg SQ at week 0, 4 and 8.
Maintenance: 200 mg SC every 4 weeks from week 12 onwards.
Follow up until week 52.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Guselkumab

Primary outcome(s)
1. Deep remission measured using clinical symptom assessment (absence of symptomatic worsening) and endoscopic evaluation, at Week 52, reported both overall and stratified by treatment cohorts.

Key secondary outcome(s))
Current secondary outcomes as of 02/01/2026:
1. Absence of symptomatic worsening measured using average daily stool frequency score (SFS) and abdominal pain score (APS) for Crohn's disease, and average daily stool frequency score (SFS) and rectal bleeding score (RBS) for ulcerative colitis, at Week 52
2. Endoscopic remission measured using Simple Endoscopic Score for Crohn's Disease (SDS-CD) for Crohn's disease and Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score for ulcerative colitis, at Week 52
3. Endoscopic response measured using change from baseline in SDS-CD for Crohn's disease and UCEIS for ulcerative colitis, at Week 52
4. Absence of symptomatic worsening at any study visit measured using SFS and APS for Crohn's disease, and SFS and RBS for ulcerative colitis, at Week 4, Week 12, Week 32, and Week 52
5. Symptomatic remission among participants not in remission at baseline measured using SFS

and APS for Crohn's disease, and SFS and RBS for ulcerative colitis, at Week 12 and Week 52
6. Steroid-free remission among corticosteroid users at baseline measured using absence of corticosteroid use and meeting symptomatic remission criteria (SFS and APS for Crohn's disease, SFS and RBS for ulcerative colitis), at Week 52
7. Discontinuation of guselkumab therapy measured using study treatment records, at Week 4, Week 12, Week 32, and Week 52

Previous secondary outcomes:
1. Absence of symptomatic worsening measured using average daily stool frequency score (SFS) and abdominal pain score (APS) for Crohn's disease, and modified partial Mayo score (m-pMS) for ulcerative colitis, at Week 52
2. Endoscopic remission measured using Simple Endoscopic Score for Crohn's Disease (SDS-CD) for Crohn's disease and Mayo endoscopic subscore for ulcerative colitis, at Week 52
3. Endoscopic response measured using change from baseline in SDS-CD for Crohn's disease and Mayo endoscopic subscore for ulcerative colitis, at Week 52
4. Absence of symptomatic worsening at any study visit measured using SFS and APS for Crohn's disease, and m-pMS for ulcerative colitis, at Week 4, Week 12, Week 32, and Week 52
5. Symptomatic remission among participants not in remission at baseline measured using SFS and APS for Crohn's disease, and m-pMS for ulcerative colitis, at Week 12 and Week 52
6. Steroid-free remission among corticosteroid users at baseline measured using absence of corticosteroid use and meeting symptomatic remission criteria (SFS and APS for Crohn's disease, m-pMS for ulcerative colitis), at Week 52
7. Discontinuation of guselkumab therapy measured using study treatment records, at Week 4, Week 12, Week 32, and Week 52

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 02/01/2026:
1. Subjects of any gender aged ≥18 years.
2. Confirmed diagnosis of IBD (CD, UC, or IBDU) for at least 6 months prior to baseline visit. Subjects with IBDU will be grouped with subjects with UC. The CD proportion of patients will be capped at 75%.
3. Subjects have received ustekinumab for at least 14 weeks and who are currently on or recently discontinued ustekinumab therapy.
4. For subjects that have recently discontinued ustekinumab, the last dose of ustekinumab must have been within 12 weeks before Week 0, and no other advanced therapy (i.e., infliximab, adalimumab, golimumab, certolizumab pegol, vedolizumab, natalizumab, risankizumab, mirikizumab, tofacitinib, upadacitinib, ozanimod, etrasimod) was started since stopping ustekinumab.
5. Subjects with an inadequate response to ustekinumab who require a change in advanced therapy and are initiating guselkumab, as determined by the treating physician.
6. For subjects on off-label ustekinumab dosing (90 mg every 4 or 6 weeks (off-label dosing), enrollment will be capped at 60%.
7. Ability and willingness to give written informed consent and comply with the requirements of this study protocol.
8. Subjects who have evidence of ongoing endoscopic evidence of disease activity within 3 months prior to Week 0, defined as:

* For Crohn's Disease: Colonoscopy showing SES-CD score (excluding the presence of narrowing component) of ≥6 (or ≥4 for participants with isolated ileal disease), OR presence of ulcers larger than 5 mm in any segment.
* For Ulcerative Colitis: Colonoscopy showing Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score ≥4, OR presence of erosions or ulcers in any segment.

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6. For subjects on off-label ustekinumab dosing (90 mg every 4 or 6 weeks (off-label dosing), enrollment will be capped at 60%.
7. Ability and willingness to give written informed consent and comply with the requirements of this study protocol.
8. Subjects who have evidence of ongoing endoscopic evidence of disease activity within 3 months prior to Week 0, defined as:
* For Crohn's Disease: Colonoscopy showing SES-CD score (excluding the presence of narrowing component) of >6 (or >4 for participants with isolated ileal disease), OR presence of ulcers larger than 5 mm in any segment.
* For Ulcerative Colitis: Colonoscopy showing Mayo endoscopic subscore ≥2 in any segment, OR presence of erosions or ulcers in any segment.

Participant type(s)
Patient

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. History of prior exposure to any anti-p19 inhibitor (risankizumab or mirikizumab).
2. Subjects with formal contraindication to guselkumab per the drug label.
3. Use of guselkumab for an off-label indication, dosing regimen, or route of administration. Subjects who did not receive guselkumab induction will be excluded.
4. Subjects with an ostomy or ileo-anal pouch.
5. Subjects with a history of bowel surgery within 6 months prior to Week 0.
6. Subjects displaying clinical signs of acute severe UC, fulminant colitis or toxic megacolon within 3 months prior to Week 0.
7. Subjects who are expected to require bowel surgery by their IBD physician within the year of enrollment.
8. Subjects on 1 or more concomitant biologics.
9. Subjects with a history of colonic dysplasia (low-grade dysplasia, high-grade dysplasia, or colorectal cancer). Note: Patients with a history of indefinite for dysplasia would be eligible.
10. Subjects with formal contraindication or unwilling to undergo lower endoscopy.
11. The patient is considered by the Investigator, for any reason, to be an unsuitable candidate for the study.

Date of first enrolment
29/12/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Canada

Study participating centre
Toronto Immune and Digestive Health Institute
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Sponsor information

Organisation
TIDHI Innovation Inc.

Funder(s)

Funder type
Industry

Funder Name
Janssen Canada

Alternative Name(s)
Janssen Inc., Janssen, Janssen Ortho Inc

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date