# A phase 3, multicenter, Randomized, Efficacy Assessor-Blinded study of Risankizumab Compared to Ustekinumab for the Treatment of Adult Subjects With Moderate to Severe Crohn*s Disease who have failed anti-TNF therapy.

Published: 15-09-2020
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This study has been transitioned to CTIS with ID 2022-501645-70-00 check the CTIS register for the current data. Part 1:The objective is to compare the efficacy and safety of risankizumab versus ustekinumab over 48 weeks for the treatment of adult...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Gastrointestinal inflammatory conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON55296

**Source**
ToetsingOnline

**Brief title**
M20-259

### Condition

- Gastrointestinal inflammatory conditions

**Synonym**
Crohn's disease, form of Inflammatory Bowel Disease (IBD)

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** AbbVie Deutschland GmbH & Co. KG
**Source(s) of monetary or material Support:** AbbVie B.V.

## Intervention

**Keyword:** Crohn's Disease, Efficacy, Failed anti-TNF therapy, Risankizumab

## Outcome measures

### Primary outcome

Part 1:

1. Clinical remission (non-inferiority) at week 24: CDAI < 150

2 . Endoscopic remission (superiority) at week 48: defined as Simple Endoscopic Score for Crohn's Disease (SES-CD) <= 4 and at least a 2-point reduction versus Baseline and no sub score greater than 1 in any individual variable, as scored by a central reviewer.

Part 2:

1. Evaluation of long-term safety

### Secondary outcome

1. Achievement of clinical remission (CDA < 150) at Week 48: superiority of risankizumab vs. ustekinumab.

2. Achievement of endoscopic response at Week 48, superiority of risankizumab vs. ustekinumab.

3. Achievement of endoscopic response at Week 24, superiority of risankizumab vs. ustekinumab.

4. Achievement of steroid-free endoscopic remission Week 48, superiority of

risankizumab vs. ustekinumab.

5. Achievement of steroid-free clinical remission at Week 48, superiority of

risankizumab vs. ustekinumab.

# Study description

### Background summary

Crohn's disease (CD) is a long-lasting condition causing inflammation that can affect any part of the gut. This study will evaluate how well risankizumab works compared to ustekinumab. This study will assess change in Crohn's Disease Activity Index (CDAI).

### Study objective

This study has been transitioned to CTIS with ID 2022-501645-70-00 check the CTIS register for the current data.

Part 1:
The objective is to compare the efficacy and safety of risankizumab versus ustekinumab over 48 weeks for the treatment of adult subjects with moderate to severe Crohn's Disease (CD) who have failed anti-TNF therapy.
Part 2:
The objective is to evaluate the long-term safety of risankizumab up to 220 weeks in subjects who received risankizumab during Part 1 and have completed the Week 48 visit.

### Study design

Randomized, efficacy assessor-blinded, parallel group study.

### Intervention

In Part 1, participants assigned to risankizumab will receive intravenous (IV) doses of risankizumab at Week 0, 4,8 and subcutaneous (SC) doses every 8 weeks thereafter through Week 48. Participants assigned to ustekinumab will receive intravenous (IV) dose of ustekinumab at Week 0 and subcutaneous (SC) doses every 8 weeks thereafter through Week 48. In Part 2, participants who received risankizumab in Part 1 and completed the Week 48 visit will continue to receive SC risankizumab for up to an additional 220

weeks.

**Study burden and risks**

There may be higher treatment burden for participants in this trial compared to their standard of care. Participants will attend regular visits during the study at a hospital or clinic. The effect of the treatment will be checked by medical assessments, blood tests, checking for side effects and completing questionnaires.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

- Male or female aged >= 18 to <= 80 years of age at the Baseline visit.

- Confirmed diagnosis of Crohns disease (CD) for at least 3 months prior to Baseline.
- Crohn's disease activity index (CDAI) score 220 - 450 at Baseline.
- Confirmed diagnosis of moderate to severe Crohns Disease as assessed by stool frequency (SF), abdominal pain (AP) score, and Simple Endoscopic score for CD (SES-CD).
- Demonstrated intolerance or inadequate response to one or more anti-TNF therapies
- If female, subject must meet the contraception recommendations

### Exclusion criteria

- Subject with a current diagnosis of ulcerative colitis or indeterminate colitis.
- Subjects with unstable doses of concomitant CD therapy
- Receipt of CD approved biologic agents prior to baseline (as detailed in protocol), or any investigational - biologic or other agent or procedure prior to Baseline (as detailed in protocol)
- Subject with prior exposure to p19 and/or p40 inhibitors (e.g., risankizumab and ustekinumab).
- Subject with complications of CD (strictures, short bowel, etc)

## Study design

### Design

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| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 11-05-2021 |

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| Enrollment: | 9 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Skyrizi |
| Generic name: | Risankizumab |
| Registration: | Yes - NL outside intended use |
| Product type: | Medicine |
| Brand name: | Stelara |
| Generic name: | Ustekinumab |
| Registration: | Yes - NL intended use |

## Ethics review

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| Approved WMO Date: | 15-09-2020 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 29-10-2020 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 12-08-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 31-10-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO | |

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| Date: | 25-11-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 10-09-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EU-CTR | CTIS2022-501645-70-00 |
| EudraCT | EUCTR2020-002674-26-NL |
| ClinicalTrials.gov | NCT04524611 |
| CCMO | NL74847.056.20 |