A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of ABBV-154 in Subjects with Moderately to Severely Active Crohn's Disease (CD): AIM-CD

Published: 29-11-2021
Last updated: 25-03-2025

The primary objective of the study is to assess the efficacy, safety, and tolerability of ABBV 154 in comparison with placebo in subjects with moderately to severely active CD who had inadequate response to or were intolerant of prior biologics.

Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON51296

Source
ToetsingOnline

Brief title
AIM-CD

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders

Synonym
Crohn's Disease, enteritis regionalis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Adalimumab, Crohn's Disease, Glucocorticoid receptor modulator

Outcome measures

Primary outcome

The primary endpoint is the achievement of endoscopic response at Week 12 in the Induction Period defined as a decrease in Simple Endoscopic Score for Crohn's Disease (SES-CD17) > 50% from Baseline (or for subjects with isolated ileal disease and a Baseline SES-CD of 4, at least a 2-point reduction from Baseline).

Secondary outcome

• Achievement of clinical remission per Crohn's Disease Activity Index (CDAI) at Week 12 in the Induction Period defined as CDAI < 150.

• Achievement of clinical remission per average daily liquid or very soft stool frequency (SF) and average daily abdominal pain (AP) score (SF/AP) at Week 12 in the Induction Period defined as average daily liquid or very soft SF <= 2.8 and not worse than Baseline AND average daily AP score <= 1 and not worse than Baseline.

• Achievement of endoscopic response per SES-CD at Week 40 in the Maintenance Period.

• Achievement of clinical remission per CDAI at Week 40 in the Maintenance Period.

• Achievement of clinical remission per SF/AP at Week 40 in the Maintenance

Period.

Study description

Background summary

Crohn's disease (CD) is a long-lasting condition causing inflammation that can affect any part of the gut. CD may cause tiredness, loose stools with or without bleeding, abdominal pain, weight loss, and fever. This study evaluates how safe and effective ABBV-154 is in participants treated for moderately to severely active CD.
Adverse events and change in the disease activity will be assessed.

Study objective

The primary objective of the study is to assess the efficacy, safety, and tolerability of ABBV 154 in comparison with placebo in subjects with moderately to severely active CD who had inadequate response to or were intolerant of prior biologics.

Study design

Randomized, Double-Blind, Placebo-Controlled Study

Intervention

The study is compromised of a 12-week double-blind, placebo-controlled induction period, followed by either a 12-week double-blind re-induction period for non-responders or a 40-week double-blind placebo-controlled maintenance period for responders. In the maintenance period, responders will be randomized to receive subcutaneous placebo or ABBV-154 in 2 different doses every other week. Participants in the placebo group
who are initial responders will receive ABBV-154 in the maintenance period.

Study burden and risks

There may be higher treatment burden for participants in this trial compared to their standard of care due to study procedures. 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)
Elderly (65 years and older)

Inclusion criteria

1. Male or female between 18 and 75 years of age inclusive at the time of Screening.
2. Confirmed diagnosis of CD for at least 3 months prior to Baseline of the Induction Period.
3. CDAI score 220 to 450 at Baseline of the Induction Period.
4. Endoscopic evidence of mucosal inflammation as documented by an SES-CD of >= 6 for ileocolonic or colonic disease or SES-CD of >= 4 for isolated ileal disease as scored by a central reader. All eligible scores must exclude the presence of narrowing component.
5. Demonstrated intolerance or inadequate response to one or more of the following biologic agents: infliximab, adalimumab, certolizumab pegol,

vedolizumab, natalizumab, or ustekinumab.

Exclusion criteria

1. Subjects with prior intolerance to adalimumab are not eligible to enroll.
2. Subjects who discontinued biologic agents only for reasons other than inadequate response or intolerance (e.g., change of insurance) are not eligible to enroll.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-09-2022
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ABBV-154
Generic name:	ABBV-154

Ethics review

Approved WMO Date:	29-11-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-03-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	23-03-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-07-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-07-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	31-10-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-12-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	06-02-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-02-2023

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-03-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
EudraCT	EUCTR2021-002869-18-NL
ClinicalTrials.gov	NCT05068284
CCMO	NL79420.028.21

Study results

Date completed:	27-04-2023
Results posted:	06-08-2024

First publication
27-06-2024

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek

URL

Internal documents
File