A Multicenter, Randomized, Double-Blind, Placebo-Controlled 52-Week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Ulcerative Colitis

Published: 02-05-2018
Last updated: 19-09-2024

This study has been transitioned to CTIS with ID 2023-506994-36-00 check the CTIS register for the current data. Study M16-066 comprises three sub-studies:Sub-study 1: Randomized, double-blind, placebo-controlled maintenanceTo evaluate the efficacy...

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

Summary

ID

NL-OMON54535

Source
ToetsingOnline

Brief title
M16-066

Condition

- Gastrointestinal inflammatory conditions

Synonym
form of inflammatory Bowel Disease (IBD), Ulcerative Colitis

Research involving

Human

Sponsors and support

Primary sponsor: AbbVie B.V.
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: - Maintenance and Open-Label Extension study, - Responders of Induction Treatment, - Risankizumab, - Ulcerative Colitis

Outcome measures

Primary outcome

Sub-study 1 or 2 : Proportion of subjects with clinical remission per Adapted

Mayo score at Week 52.

Sub-study 3: Evaluation of long-term safety.

Secondary outcome

1.Proportion of subjects with endoscopic improvement at Week 52.

2. Proportion of subjects achieving histologic-endoscopic mucosal improvement

at Week 52.

3. Proportion of subjects with endoscopic remission at Week 52.

4. Proportion of subjects achieving clinical remission per Adapted Mayo score

at Week 52 with no corticosteroid use

for 90 days.

5. Proportion of subjects with clinical remission per Adapted Mayo score at

Week 52 in subjects with clinical

remission at Week 0.

6. Proportion of subjects who reported no bowel urgency at Week 52

7. Proportion of subjects who reported no abdominal pain at Week 52

8. Proportion of subjects achieving histologic-endoscopic mucosal remission at Week 52.

9. Proportion of subjects with endoscopic improvement at Week 52 in subjects with endoscopic improvement at Week 0.

10. Proportion of subjects with clinical response per Adapted Mayo score at Week 52

11. Change from Baseline (of induction) to Week 52 in FACIT-Fatigue.

12. Change from Baseline (of induction) to Week 52 in Inflammatory Bowel Disease Questionnaire (IBDQ) total score.

13. Proportion of subjects who reported no nocturnal bowel movements at Week 52.

14. Proportion of subjects who reported no tenesmus at Week 52.

15. Change from Baseline (of induction) to Week 52 in number of fecal incontinence episodes per Week.

16. Change from Baseline (of induction) to Week 52 in number of days over a week with sleep interrupted due to UC symptoms.

17. Proportion of subjects with exposure adjusted occurrence of UC-related hospitalizations through Week 52.

Study description

Background summary

UC is a chronic, relapsing inflammatory disease of the large intestine characterized by inflammation and ulceration of mainly the mucosal and occasionally submucosal intestinal layers. The clinical course is marked by exacerbation and remission.
The aim of medical treatment in UC is to control inflammation and reduce symptoms. Available pharmaceutical therapies are limited, do not always completely abate the inflammatory process, and may have significant adverse effects. Thus, there remains a clear medical need for additional therapeutic options in UC for patients with inadequate response to or intolerance to conventional therapies and biologic therapies.

Study objective

This study has been transitioned to CTIS with ID 2023-506994-36-00 check the CTIS register for the current data.

Study M16-066 comprises three sub-studies:
Sub-study 1: Randomized, double-blind, placebo-controlled maintenance
To evaluate the efficacy and safety of risankizumab versus placebo as maintenance therapy in subjects with moderately to severely active ulcerative colitis (UC) who responded to IV risankizumab induction treatment in Study M16-067.

Sub-study 2: Randomized, exploratory maintenance
To evaluate the efficacy and safety of two different dosing regimens for risankizumab (therapeutic drug monitoring vs clinical assessment for dose escalation) as maintenance therapy in subjects with moderately to severely active UC who responded to induction treatment in Study M16-067.

Sub-study 3: Open-label long term extension
To evaluate long-term safety of risankizumab in subjects who completed Sub-study 1 or 2 or subjects responded to induction treatment in study M16-067 with no final endoscopy due to coronavirus COVD-19 pandemic or due to the geo-political conflict in Ukraine and surrounding impacted regions. Additional objectives are to further investigate longterm efficacy and tolerability of risankizumab.
The CTE is an open-label extension for Substudy 3 completers to ensure continuous treatment with risankizumab until such time that risankizumab becomes commercially available and/or the subject can access treatment locally or can transition to a Continued Treatment for Trial Participants Open-Label Extension study.

Study design

This is a phase 3, multicenter, randomized, double-blind, placebo controlled 52-week maintenance and open-label extension study to assess the efficacy and

safety of risankizumab in subjects with Ulcerative Colitis who responded to induction treatment in M16-067.

Intervention

Subjects receive once every eight weeks SC risankizumab or SC placebo. They receive this medication until the end of the study or till premature discontinuation. For subjects requiring rescue therapy, they will receive once risankizumab IV followed by once every 8 weeks SC Risankizumab.

Study burden and risks

There will be higher burden for subjects participating in this trial compared to their standard of care. Subjects will be visiting the hospital more frequently. During these visits study procedures will be performed including blood sampling and filling in questionnaires. Subjects will also be tested for TB and pregnancy. Subjects will also complete a daily diary. Women of Childbearing Potential should practice a method of birth control, during the study through at least 140 days after the last dose of study drug.
Subjects will either receive risankizumab and/or placebo during the study. The most common side effects reported during previous studies of risankizumab were nausea, abdominal pain, joint pain and headache.
The hypothesis that risankizumab should be effective in treating inflammation in patients with ulcerative colitis who are unable to tolerate or who have had an insufficient response to treatment with some currently available medications, indicates that there is an acceptable rationale to conduct this study. The risks and burden associated with participating in this study are acceptable in regards to the potential benefit study subjects could possibly have.

Contacts

Public
AbbVie B.V.

Wegalaan 9
Hoofddorp 2132 JD
NL
Scientific
AbbVie B.V.

Wegalaan 9
Hoofddorp 2132 JD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Entry and completion of Study M16-067. Completion includes the final endoscopy of Study M16-067. If the final endoscopy for Study M16-067 is missing during COVID-19 pandemic, or due to the geo-political conflict in Ukraine and surrounding impacted regions, subjects may be allowed to enroll in Sub-study 3 should they meet clinical response per Partial Adapted Mayo Score.
- Achieved clinical response at the last visit of Study M16-067

Exclusion criteria

- Subject is considered by the Investigator, for any reason, to be an unsuitable candidate for the study.
- Subject who has a known hypersensitivity to risankizumab or the excipients of any of the study drugs or the ingredients of CHO, or had an AE during Study M16-067 that in the Investigator's judgment makes the subject unsuitable for this study.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-05-2019
Enrollment:	17
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Placebo
Generic name:	Placebo
Product type:	Medicine
Brand name:	Risankizumab
Generic name:	Risankizumab

Ethics review

Approved WMO Date:	02-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-09-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	13-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	11-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-02-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam

020 566 7389

mecamc@amsterdamumc.nl

Approved WMO
Date: 08-05-2023

Application type: Amendment

Review commission: MEC Academisch Medisch Centrum (Amsterdam)

Kamer G4-214

Postbus 22660

1100 DD Amsterdam

020 566 7389

mecamc@amsterdamumc.nl

Approved WMO
Date: 26-05-2023

Application type: Amendment

Review commission: MEC Academisch Medisch Centrum (Amsterdam)

Kamer G4-214

Postbus 22660

1100 DD Amsterdam

020 566 7389

mecamc@amsterdamumc.nl

Approved WMO
Date: 14-07-2023

Application type: Amendment

Review commission: MEC Academisch Medisch Centrum (Amsterdam)

Kamer G4-214

Postbus 22660

1100 DD Amsterdam

020 566 7389

mecamc@amsterdamumc.nl

Approved WMO
Date: 21-07-2023

Application type: Amendment

Review commission: MEC Academisch Medisch Centrum (Amsterdam)

Kamer G4-214

Postbus 22660

1100 DD Amsterdam

020 566 7389

mecamc@amsterdamumc.nl

Approved WMO
Date: 31-07-2023

Application type: Amendment

Review commission: MEC Academisch Medisch Centrum (Amsterdam)

Kamer G4-214

Postbus 22660

1100 DD Amsterdam

020 566 7389

mecamc@amsterdamumc.nl

Approved WMO
Date: 30-12-2023

Application type: Amendment

Review commission: MEC Academisch Medisch Centrum (Amsterdam)

Kamer G4-214

Postbus 22660

1100 DD Amsterdam

	020 566 7389
	mecamc@amsterdamumc.nl
Approved WMO Date:	04-03-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam)
	Kamer G4-214
	Postbus 22660
	1100 DD Amsterdam
	020 566 7389
	mecamc@amsterdamumc.nl

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	CTIS2023-506994-36-00
EudraCT	EUCTR2016-004676-22-NL
ClinicalTrials.gov	NCT03398135
CCMO	NL64133.018.18