A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to Evaluate the Efficacy and Safety of Risankizumab in Subjects with Moderately to Severely Active Ulcerative Colitis

Published: 24-04-2018
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON54524

Source
ToetsingOnline

Brief title
M16-067

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: Induction Study, Risankizumab, Ulcerative Colitis

Outcome measures

Primary outcome

Proportion of subjects with clinical remission per Adapted Mayo score at Week

12.

Secondary outcome

Sub Study 1

1. Percentage of Subjects with Endoscopic Improvement at Week 12

2. Percentage of Subjects Achieving Clinical Remission at Week 12 in Subjects

with a Full Mayo Score of 6 to 12 at Baseline

3. Percentage of Subjects Achieving Clinical Response at Week 12

4. Percentage of Subjects Achieving Clinical Response at Week 4

5. Percentage of Subjects in Endoscopic Remission at Week 12

6. Percentage of Subjects with Hospitalizations through Week 12

7. Percentage of Subjects Achieving histologic endoscopic mucosal remission

(HEMR) at Week 12

8. Change from Baseline in 'UC-Symptom Questionnaire (UC-SQ)' at week 12

9. Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ)

at Week 12

10. Change from Baseline in Short Form-36 at Week 12

11. Change from Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT Fatigue)' at Week 12

12. Percentage of Subjects with UC-Related Surgery Through Week 12

Sub study 2

1. Percentage of Subjects Achieving Clinical Response at Week 12 by Adapted Mayo Score

2. Percentage of Subjects with Endoscopic Improvement at Week 12

3. Percentage of Subjects Achieving histologic endoscopic mucosal improvement (HEMI) at Week 12

4. Percentage of Subjects with Endoscopic Remission at Week 12

5. Percentage of Subjects Achieving Clinical Response at Week 4 by Partial Adapted Mayo Score

6. Percentage of Subjects Reporting No Bowel Urgency at Week 12

7. Percentage of Subjects Reporting No Abdominal Pain at Week 12

8. Percentage of Subjects Achieving histologic endoscopic mucosal remission (HEMR) at Week 12

9. Change from Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT Fatigue) at Week 12

10. Change from Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) at Week 12

11. Percentage of Subjects with UC-Related hospitalizations through Week 12

12. Percentage of subjects who reported no nocturnal bowel movements at week 12

13. Percentage of subjects who did not report tenesmus at week 12

14. Change from Baseline in Number of Fecal Incontinence Episodes per Week at

Week 12

15. Change from Baseline in Number of Days Per Week During Sleep Interruption

Due to UC Symptoms at Week 12

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

Study M16-067 comprises two sub-studies:
1) The objective of Sub-Study 1 are to characterize the efficacy, safety, and pharmacokinetics of risankizumab as induction treatment in subjects with moderately to severely active ulcerative colitis (UC) and to identify the appropriate induction dose of risankizumab for further evaluation in Sub-Study 2.
2) The objective of Sub-Study 2 is to evaluate the efficacy and safety of risankizumab compared to placebo in inducing clinical remission in subjects with moderately to severely active UC

Study design

This is a Phase 2b/3, multicenter, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of risankizumab as induction therapy in adult subjects with moderately to severely active UC.

Intervention

Subjects receive risankizumab or placebo, via IV, during the 12 week induction period (weeks 0 to 12); subjects with inadequate response receive risankizumab, via IV or SC, during the 12 week induction period 2 (week 12 to 24).

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, significant heart conditions, pregnancy, HCV/HBV and HIV. 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

- Male or female aged >= 18 to <= 80 years, or minimum age of adult consent according to local regulations at the Baseline Visit. In addition for sub-study 2 only: Where locally permissible, subjects 16 to < 18 years of age who meet the definition of Tanner stage 5 for development at the Baseline Visit
- Confirmed diagnosis of ulcerative colitis (UC) for at least 3 months prior to Baseline.
- Active UC.
- Demonstrated intolerance or inadequate response to one or more of then following categories of drugs: aminosalicylates, oral locally acting sterioids, systemic steroids, immunomodulators, and/or biologic therapies

Exclusion criteria

- Subject with a current diagnosis of Crohn's disease (CD), inflammatory bowel disease-unclassified (IBD-U) or a history of radiation or ischemic colitis.
- Subject receiving prohibited medications and treatment.
- Extent of inflammatory disease limited to the rectum as assessed by screening endoscopy.
- Subject with currently known complications of UC.

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:	Recruitment stopped
Start date (anticipated):	11-02-2019
Enrollment:	16
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:	24-04-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-05-2018
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:	14-05-2019
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:	13-06-2019
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:	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:	17-11-2020
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:	12-04-2023
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:	19-07-2023
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:	METC Amsterdam UMC

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	EUCTR2016-004677-40-NL
ClinicalTrials.gov	NCT03398148
CCMO	NL63855.018.18