An Open Label, Single Group, Long Term Safety Extension Trial of BI655066/ABBV-066 (Risankizumab), in Patients with Moderately to Severely Active Crohn's Disease.

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

Summary

ID

NL-OMON47395

Source
ToetsingOnline

Brief title
Extension study of Risankizumab in Crohn's disease

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease - inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie
Source(s) of monetary or material Support: Tot 15 juni '17 door Boehringer Ingelheim B.V.;vanaf 16 jun '17 door AbbVie

Intervention

Keyword: Crohn's disease

Outcome measures

Primary outcome

Primary objective of this study is to evaluate long term safety of Risankizumab

in patients who have achieved clinical response or remission after use of

Risankizumab.

Secondary outcome

Secondary objectives is to further investigate long-term efficacy,

tolerability, pharmacokinetics,

pharmacodynamics and immunogenicity of Risankizumab.

Study description

Background summary

Crohn*s disease is a chronic inflammatory bowel disease (IBD) that may affect
any part of the gastrointestinal tract from
mouth to anus, causing a wide variety of symptoms.
The intensity of inflammation of the bowel can vary widely; people with Crohn's
disease experience chronic recurring
periods of *flare-ups* (fast progression of disease called acute phase) and
remission (quiet periods which nearly do not
require treatment called the chronic phase).
About 35.000 Dutch people and 15.000 Belgian people have IBD. 1000 subjects are
newly diagnosed per year. The
disease is mainly diagnosed between the age of 15-30 years.
After diagnosing the disease medicinal treatment will be started to compromise

the inflammation, and to suppress the
appearance of new inflammatory spots. In addition to that prescriptions to prevent anemia and diarrhea are also frequently
prescribed.
Nearly 80% of Crohn*s disease patients require long medicinal treatment and guidance from a medical specialist. These
drugs may work, but also have negative side effects; many patients show to be intolerant to anti-TNF, which is most
frequently prescribed.

Risankizumab is an experimental drug, what will be used in patients with Crohn*s disease for the first time. It was studied in a
clinical trial with 31 patients with psoriasis, a skin disease.
Risankizumab is a *humanized monoclonal antibody* specific to IL-23 p19; this means that Risankizumab neutralizes a protein *IL-
23 p19*, which is involved in the progression of Crohn*s disease.
Neutralizingthis protein will have effect in less decrease of the health condition of subjects with Crohn's disease.

In the preceeding trial 1311.6, the patients have shown that treatment with the study drug gives potential benefit as they have either achieved clinical response or clinical remission.

Study objective

That patients who have had clinical response or clinical remission after use with Risankizumab can continue using Risankizumab. Also long term safety of Risankizumab will be assessed in patients who were diagnosed with moderate to severe Crohn's disease.

Study design

An open label, multi-center, fase II trial. Worlwide, 56 patients will be included in this trial and 4 patients will be included in the Netherlands. The study will last for 4 years and the patients will have onsite study visits at the clinic every 8 weeks, until end of trial visit.

Intervention

Patients will receive 2 sub cutaneous injections at every study visit, which will occur every 8 weeks, until end of trial visit. One syringe contains 90 mg/ml of Risankizumab.

Study burden and risks

The burden for subjects will mainly be based on the visits a subject is

requested to bring to the hospital & the kind of
examinations a subject is requested to undergo during the trial with trial purposes:
In respect to time investments subjects will be in close contacxt with their study physician for a period of 4 years.
Depending of the specific visit, this visit will take 2 to 6 hours of the subject*s time per visit. In total every patient will be
requested to spend an estimate of 99 hours (in this timeframe of 4 years total) at the hospital for interviews with the
study staff and to undergo examinations.
During 5 visits the time spent onsite by the subject will take 4 to 6 hours per visit, due to the fact a colonoscopy needs
to be performed. The performer of the colonoscopy will most probably ask patients to bring some familiar person to the clinic with them, to
stay with the subject during the examination and to bring them home after the clinic visit.
With respect to invasive procedures, subjects will be asked to undergo more frequent colonoscopies compared to the
normal clinical standard. For this study colonoscopies are required to evaluate the effect of the investigational drug.

Risks:
As Risankizumab is an experimental drug, the subjects may suffer from adverse events. It is also not known if there are more adverse events reported as this trial will go on for 4 years. The physicians will however receive all safety updates to share with the subjects.
There is a chance that subjects experience side effects of the procedures done for a colonoscopy. The procedure for the colonoscopy is the same in this clinical trial as in a clinical setting when subjects are not participating in the trial, but as the colonoscopies will occur more frequent, the chances are that subjects may suffer more from side effects due to colonoscopy.

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. Patients with Crohn`s disease, who have successfully completed the preceding trial 1311.6. Successful treatment is defined as:
- Completion of period 2 in 1311.6 with a clinical response (drop in CDAI from baseline by but no remission (CDAI < 150) at Visit E1; or
- Completion of period 3 in 1311.6 with a clinical response (drop in CDAI from baseline by >=100) or remission (CDAI < 150) at Visit E5;2. Female patients:
a. Women of childbearing potential (not surgically sterilized and between menarche and 1 year postmenopause), that, if sexually active agree to use one of the appropriate medically accepted methods of birth control in addition to the consistent and correct use of a condom from date of screening until 20 weeks after last administration of study medication. Medically accepted methods of contraception are: ethinyl estradiol containing contraceptives, diaphragm with spermicide
substance, and intra-uterine-device, or
b. Surgically sterilized female patients with documentation of prior hysterectomy, tubal ligation or complete bilateral oophorectomy, or
c. Postmenopausal women with postmenopausal is defined as permanent
cessation = 1 year of previously occurring menses, and
d. Negative serum ß-Human Chorionic Gonadotrophin test at screening.
Serum ß-Human Chorionic Gonadotrophin (ß-HCG) pregancy test will be done at screening only in case when urine pregnancy test is positive.;Male patients:
a. Who are documented to be sterile, or
b. Who consistently and correctly use effective method of contraception (i.e. condoms) during the study and 20 weeks after last administration of study medication;3. Be able to adhere to the study visit schedule and other protocol requirements.

Exclusion criteria

1. Patients who were not compliant with key study procedures (colonoscopy, treatment compliance, endpoint assessment, contraception measures) in preceding trial 1311.6
2. Patients who could not tolerate BI 655066 treatment for tolerability or safety reasons in the preceding trial
3. Are pregnant, nursing, or planning pregnancy while enrolled in the study, or within 20 weeks after receiving the last dose of study medication.
4. Patients must agree not to receive a live virus or bacterial or BCG vaccination during the study or up to 12 months after the last administration of study drug.
5. Patients who have developed malignancy, or suspicion of active malignant disease during the preceding trial
6. Are intending to participate in any other study using an investigational agent or procedure during participation in this study.
7. Cannot adhere to the concomitant medication requirements

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-02-2016
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Risankizumab
Generic name:	Nog niet bekend

Ethics review

Approved WMO Date:	11-08-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-03-2017

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-12-2018

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-01-2019
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:	05-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-06-2019
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	EUCTR2015-001834-15-NL
ClinicalTrials.gov	NCT02513459
CCMO	NL54179.018.15

Study results

Date completed:	19-06-2019
Results posted:	17-06-2020

First publication
12-05-2020

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

Internal documents
File