An open label, long term safety trial of spesolimab treatment in patients with fistulising Crohn*s disease who have completed previous spesolimab trials.

Published: 24-02-2020
Last updated: 17-01-2025

1. To evaluate the long-term safety of spesolimab in patients with fistulising Crohn*s disease who have completed treatment in previous trials.2. To evaluate the long-term efficacy of spesolimab in patients with fistulising Crohn*s disease who have...

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

Summary

ID

NL-OMON52849

Source
ToetsingOnline

Brief title
1368-0007: Long-term spesolimab in patients with fistulising CD.

Condition

- Gastrointestinal inflammatory conditions

Synonym
chronic inflammation of digestive tract, Crohn disease

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim

Source(s) of monetary or material Support: De opdrachtgever Boehringer Ingelheim

Intervention

Keyword: Crohns disease, Long term, Phase II, Spesolimab

Outcome measures

Primary outcome

Exposure adjusted rate of patients reporting a treatment emergent adverse event

(TEAE) up to week 336 of maintenance treatment.

Secondary outcome

- Proportion of patients with perianal fistula remission at weeks 48, 96, 144,

192, 240, 288 and 336

- Proportion of patients with perianal fistula response at weeks 48, 96, 144,

192, 240, 288 and 336

- Proportion of patients with clinical remission at weeks 48, 96, 144, 192,

240, 288 and 336

- Proportion of patients with endoscopic remission at weeks 48, 96, 144, 192,

240, 288 and 336

Study description

Background summary

Fistulas represent one of the most important complications in patients with CD. The number of patients with severe and recurrent problems arising from CD fistulas is considerably high. Surgery, though often required, does not always provide a definitive cure. Current treatments with medications show limited efficacy. Thus, there remains a significant unmet Medical need for better treatments of this CD complication See also protocol section 1.1.

Study objective

1. To evaluate the long-term safety of spesolimab in patients with fistulising Crohn*s disease who have completed treatment in previous trials.
2. To evaluate the long-term efficacy of spesolimab in patients with fistulising Crohn*s disease who have completed treatment in previous trials.

Study design

This is an open label, single group, long-term extension study of approximately 7 year duration.
It is expected that a maximum of 20 patients will roll-over from study 1368-0008.
See protocol section 3.1.

Intervention

Patients will receive spesolimab maintenance treatments 300mg subcutaneously every 4 weeks for 336 weeks (approximately 7 years).
In case of a confirmed flare disease or fistula relapse a single dose of 1200mg intravenous infusion of spesolimab will be given to the patient, followed by an intensified subcutaneous maintenance treatment (600mg spesolimab subcutaneous injection every 4 weeks).
See protocol section 4.1.

Study burden and risks

Patients entering this trial will already have received a benefit from treatment with spesolimab in a preceeding trial. This, in adition to the medical need for effective and well tolerated drug specifically and directly treating the structural aspects of CD makes it conceivable to anticipate that the benefits of receiving further treatment will outweigh the risks in these patients.

Moreover, since there are no mechanism- or compound-related safety alarm signals from all available data from spesolimab, it is highly likely that eligible patients for the study, CD patients with perianal fistulising disease, will not be exposed to undue risks and adverse events.

The total duration of the study for a patient is a maximum of 336 weeks. Patients have a risk of (unknown) side effects, an allergic reaction to the study medication, pain due to blood sampling or irritated skin due to the electrodes used in making the ECGs, discomfort and (small) risk for complications during the rectoscopy/proctoscopy and biopsies.

See protocol section 1.4.

Contacts

Public
Boehringer Ingelheim

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient older than 18 years
- Has completed all treatments (placebo or active treatment) and the EOT visit in the parent induction trial in fistulising CD and is willing and able to continue treatment in 1368-0007
- Has obtained an individual health benefit, per investigator judgement (such as fistula response or remission or other clinical improvement), from treatment in the parent trial
- Signed and dated written informed consent for 1368-0007
- Women of childbearing potential (WOCBP) must be ready to use highly effective methods of birth control

Exclusion criteria

- Have experienced treatment-limiting adverse events during induction treatment with study drug
- Have developed any condition which meets the exclusion criteria from the original induction study
- Any condition which in the opinion of the investigator affects the safety or ability to participate in this trial

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):	06-12-2021
Enrollment:	1
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Spesolimab
Generic name:	Niet bekend

Ethics review

Approved WMO

Date:	24-02-2020

Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-04-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-08-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	31-08-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-11-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-11-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-07-2022
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
EudraCT	EUCTR2019-001673-93-NL
ClinicalTrials.gov	NCTnummernognietbekend
CCMO	NL72654.056.20

Study results

Date completed: 30-08-2022

Results posted: 23-03-2023

First publication
13-03-2023