A Phase 2 study to investigate the efficacy, safety, and tolerability of six weeks treatment with V565 in subjects with active Crohn*s disease

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

Summary

ID

NL-OMON47571

Source
ToetsingOnline

Brief title
V56502 - HARBOR

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's Disease, Enteritis Regionalis

Research involving
Human

Sponsors and support

Primary sponsor: VHsquared Ltd

Source(s) of monetary or material Support: Industry

Intervention

Keyword: Crohn□s Disease, enteritis regionalis, Inflammatory Bowel Disease, Targeted Anti-TNF□

Outcome measures

Primary outcome

Proportion of responders at Day 42, defined as subjects achieving both CDAI *70-

point reduction from Baseline OR CDAI score <150, AND a reduction of *40% from

the baseline value of CRP or FCP

Secondary outcome

- Proportion of subjects achieving a *100-point reduction in CDAI score and a

concomitant reduction of 50% in CRP or FCP at Day 42

- Proportion of subjects achieving a *70-point reduction in CDAI score at Day 42

- Proportion of subjects achieving a *100-point reduction in CDAI score at Day

42

- Proportion of subjects achieving a CDAI score of <150 CDAI at Day 42

- Changes from Baseline in scores for PRO-2 at Day 14 and Day 42

Study description

Background summary

Crohn*s disease (CD) is characterized by a chronic relapsing progressive course of intestinal inflammation which is increasing in incidence worldwide. If disease control is inadequate, the chronic inflammation leads to significant inflammatory, infectious and structural complications. The complications result in an increased need for hospitalization and surgery, impaired quality of life, and disease-related mortality. Persistent and extensive inflammation can even result in the development of small bowel and colorectal carcinoma.

Currently CD is being treated with parenterally administered TNF* monoclonal antibodies (e.g. infliximab and adalimumab), which have proven to be able to affect and improve long-term outcomes. It was found that observational, subgroup analyses and randomized control trial data, both in adults and in pediatric populations, indicated that TNF* antagonists are much more effective when given to patients within 1 to 2 years of their initial diagnosis. For a number of reasons including the cost of treatment and safety concerns , these treatments tend to be used late in the management of CD, when much damage has already occurred in the GI tract.

Study objective

The primary objective is to evaluate the efficacy of V565 555 mg TID in subjects with active CD measured by the proportion of subjects achieving response to therapy. Response is defined as reduction in the Crohn's Disease Activity Index (CDAI) scores and in inflammatory markers CRP or FCP at Day 42.

Study design

This study will be a multiple-site, double-blind, placebo-controlled, parallel-group proof-of-concept study in approximately 126 subjects with active CD. This study will include subjects who have a confirmed diagnosis of CD for at least three months and have CD involving the ileum and/or colon.

Intervention

Each dose will consist of three capsules of V565 (three 185-mg capsules, total dose 555 mg) or placebo. Study drug will be administered orally TID. The subjects will be instructed to take the capsules with sufficient fluid one hour before meals and at least two hours after the previous meal.
No dose adjustments are permitted.

Study burden and risks

This study has been designed to minimize potential risks to subjects. The exclusion criteria and screening procedures were designed to exclude subjects who may be at undue risk if they participate in the study.

As this is a proof-of-concept study, there may be no benefit from participation in the study to an individual subject. However, there is the expectation that subjects treated with V565 will experience improvements in the symptoms of their underlying disease.
In summary, the assessment of potential risks associated with V565 in non-clinical and clinical studies conducted to date support further evaluation in humans.
This study will be performed in compliance with the protocol, International

Council for Harmonization (ICH), Good Clinical Practice (GCP), and applicable regulatory requirements.

Contacts

Public
VHsquared Ltd

Lower Court, Copley Hill Business Park, Cambridge Road 1
Cambridge CB22 3GN
GB
Scientific
VHsquared Ltd

Lower Court, Copley Hill Business Park, Cambridge Road 1
Cambridge CB22 3GN
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. History of CD (confirmed by ileocolonoscopy) of at least three months duration prior to Visit 1
2. CDAI score of *220 to *450 during Screening
3. CRP *5 mg/L (or, if CRP is normal, FCP* 250 *g/g) at Screening
4. Active CD of ileum and/or colon as determined by the baseline ileocolonoscopy
5. Female subjects must not be pregnant and male and female subjects must agree to use effective contraception throughout the study and for 90 days after the last dose of study drug.

6. Subject must have failed or experienced intolerance to at least one of the following: aminosalicylates, corticosteroids; immunosuppressants

Exclusion criteria

1. CD of mouth, stomach, oesophagus or duodenum which, in the opinion of the Investigator, is likely to be causing symptoms
2. Known history of or suspicion of ulcerative colitis, indeterminate colitis, microscopic colitis, ischaemic co litis or radiation-induced colitis, based on medical history, endoscopy and/or histological findings.
3. Any gastrointestinal (GI) manifestations of CD that might affect the evaluation of efficacy
4. Prior primary efficacy failure of o r secondary loss of response to anti-TNF* therapy, or any contraindication to anti-TNF* therapy
5. The use of medications prior to the study or during the study with the potential to affect the evaluation of efficacy

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):	11-09-2017
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	V565
Generic name:	-

Ethics review

Approved WMO Date:	22-02-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-04-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-05-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-06-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-09-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-01-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	17-01-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-02-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-03-2018
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	EUCTR2016-002939-15-NL
ClinicalTrials.gov	NCT02976129
CCMO	NL60562.056.17