Therapeutic drug monitoring of vedolizumab in patients with inflammatory bowel disease

Published: 03-02-2021
Last updated: 08-04-2024

The aim of this study is to determine whether there is a correlation between vedolizumab trough level and disease activity in a typical inflammatory bowel disease (IBD) population. In addition, the extent to which patient characteristics and co-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON55193

Source
ToetsingOnline

Brief title
TUMMY

Condition

- Gastrointestinal inflammatory conditions

Synonym
chronic bowel diseases, Inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Commissie Onderzoek en Innovatie fonds

Intervention

Keyword: colitis ulcerosa, Crohn's disease, TDM, vedolizumab

Outcome measures

Primary outcome

The correlation between vedolizumab trough level and disease activity in IBD patients on maintenance therapy with vedolizumab

Secondary outcome

Influence of the following parameters on this correlation:

- patient characteristics such as gender, weight, age, smoking status, duration of illness, biological therapy in history, CRP, albumin, Hb, calprotectin.

- medications such as immunosuppressants and corticosteroids

- vedolizumab dosing frequency

The mean vedolizumab trough level in patients with active disease compared to patients in remission

The cut-off value for an effective vedolizumab trough level (including positive and negative predictive value). The patient is considered adequately treated with an HBI <5, SCCAI <2, CRP <5.

Study description

Background summary

Vedolizumab is often used in inflammatory bowel diseases after failure of anti-TNF therapy. In anti-TNF therapy, in particular infliximab, reactive therapeutic drug monitoring is already extensively used, ie in therapy failure or sub-optimal therapy. This involves monitoring anti-TNF trough levels and anti-TNF antibodies to optimize therapy. Vedolizumab is used in a standard dose of 300 mg at weeks 0, 2 and 6 as induction, after that the therapy is switched

to maintenance therapy of 300 mg every 8 weeks. In addition, in the regular treatment protocol for Crohn's patients with a reduced response, the possibility is given to administer an extra dose at week 10. Also, after induction, the treatment frequency can be shortened to every 4 weeks when patients show a reduced response in both Crohn's disease and ulcerative colitis. Various studies show that there is a concentration effect relationship in vedolizumab therapy. Despite indications in the literature, this is not yet standard practice in the hospital. The use of therapeutic drug monitoring of vedolizumab in the treatment of inflammatory bowel disease has the potential to individualize and optimize this treatment.

Study objective

The aim of this study is to determine whether there is a correlation between vedolizumab trough level and disease activity in a typical inflammatory bowel disease (IBD) population. In addition, the extent to which patient characteristics and co-medication influence the trough level and thus possibly the disease activity is also examined. Finally, if a correlation exists, an attempt will be made to define a cut-off value.

The primary aim of the study is to describe the association between vedolizumab trough level and disease remission in the population of IBD patients receiving maintenance treatment with vedolizumab (ie, both ulcerative colitis and Crohn's).

Secondary aim is to describe the association between vedolizumab trough level and disease activity rate. Because disease activity is presented differently for the different types of IBD, this analysis is stratified for Crohn's and ulcerative colitis.

Study design

This concerns a prospective, observational cross-sectional multicentre study.

Study burden and risks

nvt

Contacts

Public
Maxima Medisch Centrum

De Run 4600

Veldhoven 5500MB
NL
Scientific
Maxima Medisch Centrum

De Run 4600
Veldhoven 5500MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

age *18 years, maintenance therapy of vedolizumab (>14 weeks), diagnosed with Crohn's disease (DBC 601) or colitis ulcerosa (DBC602)

Exclusion criteria

age <18 years, induction therapy with vedolizumab (<14 weeks), incapable of consenting

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2021
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	03-02-2021
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL74886.015.20
Other	NL8820