Therapeutic drug monitoring of vedolizumab in patients with inflammatory bowel disease

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28041

Source
Nationaal Trial Register

Brief title
TUMMY

Health condition

Colitis ulcerosa and Crohn's disease

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Hospital budget

Intervention

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
- quality of life (NRS)

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 <5, CRP <5.

Study description

Background summary

edolizumab 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. The aim of this study is to determine whether there is a correlation between vedolizumab trough level and disease activity in a typical 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.

Study objective

The hypothesis is that higher vedolizumab through levels correlate with better disease management

Study design

One point measurement

Contacts

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Eligibility criteria

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), disabled persons.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	13-09-2020
Enrollment:	160
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8820
Other	METC Máxima MC : To be assisgned

Study results