Therapeutic drug monitoring of vedolizumab in patients with inflammatory bowel disease

Gepubliceerd: 07-08-2020 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28041

Bron
Nationaal Trial Register

Verkorte titel
TUMMY

Aandoening

Colitis ulcerosa and Crohn's disease

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: Hospital budget

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

maintenance therapy with vedolizumab

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

One point measurement

Contactpersonen

Publiek

Máxima MC
Merve Sivridas

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

age <18 years, induction therapy with vedolizumab (<14 weeks), disabled persons.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	13-09-2020

Aantal proefpersonen:	160
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8820
Ander register	METC Máxima MC : To be assisgned

Resultaten