Bullseye study

Gepubliceerd: 23-05-2018 Laatst bijgewerkt: 19-03-2025

Crohn's disease is an immune-mediated disease that results in chronic inflammation in genetically predisposed individuals exposed to an appropriate environment. The introduction of monoclonal antibodies has revolutionized the treatment of Crohn...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25877

Bron
NTR

Aandoening

Inflammatory Bowel Diseases; Crohn's Disease; Ziekte van Crohn; Chronische darmontsteking; Inflammatoire darmziekten; vedolizumab; Entyvio; systems medicine

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: Takeda Nederland BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To identify biomarkers predicting response to vedolizumab in patients with CD

Toelichting onderzoek

Achtergrond van het onderzoek

See hypothesis.

Doel van het onderzoek

Crohn's disease is an immune-mediated disease that results in chronic inflammation in genetically predisposed individuals exposed to an appropriate environment. The introduction of monoclonal antibodies has revolutionized the treatment of Crohn’s disease (CD). Unfortunately, the efficacy of these agents is hampered by loss of response in a significant proportion of patients. Recently, vedolizumab, an integrin á4â7 antagonist, has been licensed for the treatment of CD and UC. Response rates vary between 31% for CD and 47% for UC at week 6 (1;2). In biological-naive patients, response rates may be up to 40% at week 6 and 47% at week 10 (unpublished results from Gemini 2 en 3 studies). However, a considerable proportion of patients does not respond to vedolizumab. Since the use of vedolizumab is associated with substantial financial expenditures, tools to identify patients in whom the drug will be effective are warranted.

Hypothesis:

Response and non-response to vedolizumab can be predicted using biomarkers, identified through a System Medicine approach.

Onderzoeksopzet

Prior to starting therapy; week 2, week 6, week 22, week 52

Onderzoeksproduct en/of interventie

Vedolizumab therapy

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult CD patients with luminal disease, who are anti-TNF therapy naïve, with an indication for step-up to vedolizumab will be recruited.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- No consent to participate in the study

- Hospitalized patients or patients in need of surgery

- Active perianal disease

- Prior biological use

- Recent use of antibiotics (within 4 weeks of baseline)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2017
Aantal proefpersonen:	65
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-05-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50386
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6439
NTR-old	NTR7229
CCMO	NL60968.041.17
OMON	NL-OMON50386

Resultaten