Bullseye study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25877

Source
NTR

Health condition

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

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: Takeda Nederland BV

Intervention

Outcome measures

Primary outcome

To identify biomarkers predicting response to vedolizumab in patients with CD

Secondary outcome

To gain insight in pathways, associated with (non)reponse to vedolizumab in patients with CD

Study description

Background summary

See hypothesis.

Study objective

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 In biological-naive patients, response rates may be up to 40% at week 6 and 47% at week 10 (unpublished results from Gemini 2 en 3 studies).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.

Study design

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

Intervention

Vedolizumab therapy

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2017
Enrollment:	65
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-05-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50386
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results