Clinical Validation of a Point of Care (POC) Test for the Measurement of Infliximab (IFX) or Adalimumab (ADL) Levels in the Serum of Inflammatory Bowel Disease (IBD) Patients

Gepubliceerd: 14-09-2020 Laatst bijgewerkt: 13-12-2022

The hypothesis is that patients with low anti-TNF drug levels have a higher risk of loss-of-response to anti-TNF drugs compared to patients with high anti-TNF drug levels.

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

Samenvatting

ID

NL-OMON20824

Bron
Nationaal Trial Register

Verkorte titel
PROCISE

Aandoening

inflammatory bowel disease

Ondersteuning

Primaire sponsor: ProciseDx
Overige ondersteuning: ProciseDx

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Proportion of patients developing Loss of Response (LOR) to IFX or ADL.

Loss of response is a composite endpoint defined as:
1) Stopping IFX or ADL therapy due to worsening symptoms and abnormal endoscopy/imaging/biomarker indicating increased disease activity or
2) Need for addition of corticosteroids, and/or addition immunomodulators (thiopurines or methotrexate), and/or addition of a second biologic due to worsening symptoms and abnormal endoscopy/biomarker results indicating increased disease activity or
3) Increase in fecal calprotectin concentration of ≥100 mg/Gr to a value >250mg/Gr
4) Need for surgery (intestinal resection, fistulotomy, stricturoplasty) due to IBD exacerbation or
5) New or recurring actively-draining fistula or
6) Endoscopic deterioration compared to previous endoscopy – both performed during anti-TNF maintenance treatment – defined by a total SES CD score increase of ≥50% or endoscopic mayo score increase ≥1

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Measurement of infliximab (IFX) and adalimumab (ADL) can be used as an aid in the management of inflammatory bowel disease (IBD).

Objective:
To evaluate the relationship between the Procise IFX Test or Procise ADL test results and changes in the state of the patients' IBD and to validate the use of the IFX or ADL test for the monitoring of serum levels of IFX or ADL as an aid in the management of IBD.

Study design:
Retrospective observational study.

Observation time:
Observational period starts at the fist available serum sample taken between 2016 and 2018. Patients are required to have a follow up of at least 24 months.

Study population:
Serum samples of 320 adult (≥ 16 years old) patients with a confirmed diagnosis of IBD and treated with maintenance IFX or ADL therapy (160 IFX (including biosimilars) & 160 ADL (including biosimilars)) that were previously collected and stored frozen with ≥ 24 months follow up

Main study parameters/endpoints:
Primary outcome: Proportion of patients developing Loss of Response (LOR) to IFX or ADL

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The entire study is retrospective with no additional risks or burden for participants. However, serum was collected as part of standard medical care and not for research purposes. Hence, written informed consent is obtained to use these serum samples for the objective as specified in this study protocol and to conduct retrospective medical chart review.

Doel van het onderzoek

The hypothesis is that patients with low anti-TNF drug levels have a higher risk of loss-of-response to anti-TNF drugs compared to patients with high anti-TNF drug levels.

Onderzoeksopzet

Observational (standard of care)

Observational period starts at the fist available serum sample taken between 2016 and 2018. Patients are required to have a follow up of at least 24 months.

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

Publiek

Amsterdam UMC, location AMC
Toer Stevens

0205665584

Wetenschappelijk

Amsterdam UMC, location AMC
Toer Stevens

0205665584

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Adult (≥16 years old) Males and females with either CD or UC.
2. Patients must have a confirmed diagnosis of CD or UC based on results of a complete medical evaluation and assessment by a physician specialized in inflammatory bowel disease.
3. Patients must be undergoing maintenance phase IFX or ADL therapy at the time of the first blood collection used for the current study
4. Patients must have at least 24 months of follow up after the baseline sample.
5. Written informed consent must be provided.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients not undergoing maintenance phase IFX, ADL or biosimilar therapy at time of baseline sample collection.
2. Patients not diagnosed with either CD or UC.
3. Receipt of any blood products within 3 months prior to the baseline sample collection
4. Participation in a clinical trial at the baseline sample collection or within the 8 weeks prior to the baseline sample collection.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	14-09-2020

Aantal proefpersonen:	320
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-09-2020
Soort:	Eerste indiening

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	NL8934
Ander register	METC AMC : W20_314

Resultaten