A Prediction Model to Safely CEASE Anti-TNF Therapy in Patients with Crohn's Disease

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25895

Bron
Nationaal Trial Register

Verkorte titel
CEASE

Aandoening

Crohn's Disease

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC and Erasmus MC
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is a documented relapse of CD or CD complications, which necessitates medical or surgical intervention.

A relapse of luminal CD is defined as:
- Clinical relapse; HBI ≥ 5, on two consecutive measurements, with two weeks between both measurements, AND
- Biochemical relapse; FCP ≥ 250 µg/g on two consecutive measurements, with two weeks between both measurements, OR
- Endoscopic relapse; ulcerations on endoscopy.

CD complications include the following:
- Active fistula
- Perianal abscess
- Extra-intestinal manifestations, including but not limited to pyoderma gangrenosum, erythema nodosum.

Toelichting onderzoek

Achtergrond van het onderzoek

In the Netherlands, approximately 25-30% of Crohn's Disease (CD) patients receive anti-TNF therapy (infliximab or adalimumab). Despite the positive effects of anti-TNF treatment on the disease course, long-term anti-TNF treatment can lead to severe side effects such as infections, infusion reactions and possibly increased risk of melanoma. Furthermore, biologicals such as anti-TNF are rather expensive, especially since CD patients are treated long-term and clear stop-criteria are not available to date. The CEASE project has been designed to develop, validate and implement a diagnostic tool to safely cease anti-TNF therapy in CD patients. In phase 0 of the CEASE trial, the diagnostic tool was developed by using a IPD-MA. Subsequently, this model has been externally validated in a retrospective Dutch cohort. In this trial, we will assess the prognostic performance of the diagnostic tool to predict a relapse. For this, we will perform a multicentre, centre-specific stepped wedge randomized controlled trial. The participating centres will be randomly assigned to three groups, which will implement the anti-TNF stop strategy with the CEASE tool at three different time points. In the first part of the trial, patients will continue their treatment as usual (control group) with a follow-up time of either 6, 12 or 18 months. In the second part of the trial, a new group of patients will stop their anti-TNF therapy (intervention group) and these will have a follow-up time of 18, 12 or 6 months, with respect to the cluster the hospital has been randomized to.

Doel van het onderzoek

In Phase 1, we found that the proportion of low-risk patients that experience a relapse of CD after stopping anti-TNF therapy (> 6 months stable) was 28% at 1 year of follow-up. The proportion of low risk patients who experience a relapse of CD with continuous anti-TNF

therapy (>1 year stable) is unknown; we expect it to be around 13% per year by using the diagnostic tool.

Onderzoeksopzet

Screening, baseline, 3, 6, 9, 12, 15, 18 months
(However, this depends on the cluster the hospital has been randomized to; subjects with 6 months follow up will have their last visit at 6 months, etc.)

Onderzoeksproduct en/of interventie

Cessation of anti-TNF

Contactpersonen

Publiek

Amsterdam UMC, location AMC
Djuna de Jong

020-5661260

Wetenschappelijk

Amsterdam UMC, location AMC
Djuna de Jong

020-5661260

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Anti-TNF therapy ≥12 months
2. For low risk: Relapse risk < 33.3% after cessation of anti-TNF as predicted by the CEASE tool (‘low risk’, see Appendix 2).
3. Age ≥ 16 years.
4. Ability and willingness to give informed consent.
5. Luminal CD as indication for anti-TNF therapy.

6. Duration of anti-TNF treatment ≥ 12 months and a stable dose ≥ 3 months.
7. Concomitant therapy with an immunosuppressant is allowed (stable dose ≥ 3 months) and will be continued after withdrawal of anti-TNF medication during the study period.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Ulcerative colitis or IBD-unclassified
2. Co-morbidities that are a contraindication for (dis)continuing anti-TNF therapy
3. Corticosteroid use for luminal CD 6 months prior to inclusion
4. Ongoing pregnancy or planned pregnancy for the duration of the study
5. In the opinion of the investigator, the participant is incapable of understanding and complying with protocol requirements.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	190
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	NL8891
Ander register	METC Erasmus MC : MEC-2020-0575

Resultaten