

The effect of body composition on infliximab (remicade/inflectra) on inflamamtory bowel disease (Crohn's disease, Colitis Ulcerosa)

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

Samenvatting

ID

NL-OMON28109

Bron

Nationaal Trial Register

Verkorte titel

FLINX

Aandoening

Inflammatory bowel disease,
Crohn's disease
Colitis Ulcerosa

Ondersteuning

Primaire sponsor: Zuyderland Medisch Centrum
Afdeling MDL en Klinische farmacologie

Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is the correlation between fat mass, measured by an validated body composition monitor(BCM), and the IFX level. This will be measured prior to the IFX infusion. The IFX concentration will be measured and analysed in blood. Prior to de IFX infusion the trough level will be measured (according to regular health care). 30 minutes after the end of the infusion the top level will be measured.

Toelichting onderzoek

Achtergrond van het onderzoek

Background and problem statement:

Patients suffering from inflammatory bowel disease (IBD) are treated with anti-TNFalpha (TNFi) medication in 10-30% of the cases. In the current practice the dose of most of the TNFi medications are based on the weight of the patients, Infliximab (IFX) in particular. However, some studies show that this dose is not optimal. Therefore, other methods must be investigated.

Research question :

What is the relation between of body composition(body fat mass) and the IFX level, with the IFX dose based on the body weight, in an IBD population using IFX medication? Secondly; Is the effectiveness of IFX related to the body composition in IBD patients starting with TNFi medication?

Setting of the research and subjects:

In this observational study patients receiving IFX infusion every 8 weeks and patients starting with IFX for the treatment of ulcerative colitis or Crohn's disease will be included. The relation between body composition and IFX level will be measured in patients receiving IFX infusion every 8 weeks following a transversal study design. Furthermore, patients starting with IFX need to receive a loading dose of 3 gifts in order to reach a steady state. Therefore the IFX level will be measured after the third IFX infusion. In this patient group, the effect of IFX related to the body composition can be investigated.

Methods of data collection

Body composition will be measured with non-invasive methods; validated scale for fat mass,

skinfold measure, squeezing force and waist circumference. To calculate BMI and body surface; length and bodyweight will be measured. Prior to the IFX infusion, the trough level will be determined, according to regular care. 30 minutes after the end of the infusion the top level will be determined. The inflammation parameters to evaluate the effectiveness are CRP in blood and calprotectin in feces and will be measured following regular healthcare.

Doel van het onderzoek

It is described in the literature that determining the dosage of IFX based on body weight does not seem ideal. Therefore other methods must be investigated in order to determine a more optimal dosage. The aim of this study is to investigate the relation between body composition, body surface and BMI and the IFX serum level. Besides, there will be investigated if body composition and BMI, and their possible pharmacokinetic consequences influence the effectiveness of the IFX medication in the IBD population.

We hypothesize that there is a stronger relation between body composition and IFX than there is with bodyweight and IFX.

Onderzoeksopzet

T0: Prior to IFX infusion

- Body composition (fat mass by BCM, skinfold thickness, waist circumference, hand grip strength), height and weight
- Inflammation parameters (CRP, calprotectin)
- Trough level IFX

T1: 30 minutes after IFX infusion

- Top level IFX

T2: after IFX infusion

- Inflammation parameters (CRP, calprotectin)
- Adverse effects

Onderzoeksproduct en/of interventie

Not applicable (observational study)

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patiënt are eligible to participate in the study if all of the following criteria are met:

1. Patient, male or female, is aged above 18 years
2. Patient has an established diagnosis of ulcerative colitis or Crohn's disease
3. Patients is being treated with, or start with the treatment IFX for a period of at least 12 weeks, or for the first time during the study period.
4. Patiënt must be able to understand the patient information and the explanation of the investigator
5. Patient must be able to undergo the study measurements and understand the instructions of the investigator
6. Patient is informed about the intention and nature of the study including the possible risks and has signed the informed consent before inclusion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients are not eligible if one or more of the following criteria are met:

1. Patient is mentally or physically not able to participate to the study, including severe

mental illness.

2. Patient has had a change in the dosage of the IFX during the last 5 weeks.

3. Patients who is currently pregnant, breastfeeding, or is planning to become pregnant during the study period.

4. Patients suffering from severe comorbidities which can influence the body composition of the pharmacokinetics of IFX;

a. Current malignancy or a malignancy in the recent history (<5 years), except cutaneous basal cell carcinoma and cutaneous squamous cell carcinoma.

b. (history of) Liver/renal failure

c. Short Bowel Syndrome

d. Heart failure defined as; New York Heart Association (NYHA) Class III or IV

5. Patients participating in other studies, or participated in another study with an intervention in the last 4 months.

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: 18-01-2019

Aantal proefpersonen: 33

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 23-11-2018

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46317

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6757
NTR-old	NTR7626
CCMO	NL66944.096.18
OMON	NL-OMON46317

Resultaten