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

No registrations found.

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

Summary

ID

NL-OMON28109

Source
Nationaal Trial Register

Brief title
FLINX

Health condition

Inflammatory bowel disease,
Crohn's disease
Colitis Ulcerosa

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Afdeling MDL en Klinische farmacologie
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondarily, the body composition(skinfold thickness, waist circumference, hand grip strength), BMI and body surface will be correlated to the IFX concentration. Furthermore, the disease activity, inflammation parameters and the amount of adverse effects will be measured en correlated to the fat mass.

Study description

Background summary

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? Secondarily; 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.

Study objective

It is described in the literature that determining the dosage of IFX based on body weight does not seems 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 hypothesis that there is a stronger relation between body composition and IFX than there is with bodyweight and IFX.

Study design

T0: Prior to IFX infusion

- Body composition (fat mass by BCM, skinfold thickness, waist circumference, hand grip strength), height and weigth

- Inflammation parameters (CRP calprotectine)

- Trough level IFX

T1: 30 minutes after IFX infusion

- Top level IFX

T2: after IFX infusion

- Inflammation parameters (CRP calprotectine)

- Adverse effects

Intervention

Not applicable (observational study)

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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 I another study with an intervention in de last 4 months.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2019
Enrollment:	33
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-11-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46317
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results