Correlation of a predefined set of 96 inflammatory proteins between the serum and intestinal tissue within patients with inflammatory bowel disease

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22599

Bron
Nationaal Trial Register

Verkorte titel
ASCERTAIN

Aandoening

inflammatory bowel disease

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess the correlation of protein profiles between intestinal tissue and serum in patients with IBD

Toelichting onderzoek

Achtergrond van het onderzoek

Inflammatory bowel disease (IBD) comprise two major entities of chronic intestinal disorders: Crohn¡¯s disease (CD) and ulcerative colitis (UC). The ongoing expansion in the therapeutic armamentarium for IBD has improved therapeutic outcome for many patients. However, both CD and UC are highly heterogenic conditions, both in clinical presentation and in response to therapy. It remains difficult to predict which patient is likely to respond to a particular treatment at any given stage of their disease. To optimize the use of currently available therapeutic interventions, a more personalized diagnostic and therapeutic care-path is needed. Currently it may take several years to find an effective treatment for an individual patient. Hence, from both a patient and a pharmaco-economic point of view, predictive biomarkers for therapy response would be of great benefit. Most studies that aimed to discover new IBD biomarkers on a protein level have mainly focused on plasma/serum. However, recent studies suggest that analysing material closer to or directly from the location of disease may yield higher concentrations of potential biomarkers. However, although the diseased intestine itself may contain increased protein concentrations and facilitate biomarker discovery, the use of this material in routine care is limited due to the invasive nature of the procedure. Therefore, matched validation of candidate markers in serum is required. We aim to investigate the correlation between the protein profiles of the serum and the gut mucosa.

Doel van het onderzoek

Most studies that aimed to discover new IBD biomarkers on a protein level have mainly focused on plasma/serum. However, recent studies suggest that analysing material closer to or directly from the location of disease may yield higher concentrations of potential biomarkers. However, although the diseased intestine itself may contain increased protein concentrations and facilitate biomarker discovery, the use of this material in routine care is limited due to the invasive nature of the procedure. Therefore, matched validation of candidate markers in serum is required. We aim to investigate the correlation between the protein profiles of the serum and the gut mucosa.

Onderzoeksopzet

Cross sectional

Onderzoeksproduct en/of interventie

procurement of 5 intestinal biopsies

1 5mL serum tube withdrawal

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients ¡Ý 18 years old

2. Diagnosis of IBD, based on a combination of history, physical examination, family history, laboratory tests, endoscopy tests including histopathologic examination of mucosal biopsies, imaging studies and occasionally intraoperative findings

3. Written informed consent

4. The clinical indication for a colonoscopy, independent of this study

5. Active disease, defined by either clinical or biochemical AND endoscopic signs:

5.1 Clinical OR biochemical signs of active disease

5.1.1 Clinical:

5.1.1.1 CD: Harvey Bradshaw index (HBI) [21] > 4

5.1.1.2 UC: simple clinical colitis activity index (SCCAI) [22] ¡Ý 5

5.1.2 Biochemical:

5.1.2.1 CRP > 5 mg/L or fecal calprotectin (FC) > 250 mcg/g)

AND

5.2 Endoscopic signs of active disease

5.2.1 CD: ¡Ý 1 ulcer ¡Ý 0.5 cm

5.2.2 UC: Mayo score [7] ¡Ý 1

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years at inclusion

2. Ongoing use of anticoagulants that may increase the risk of bleeding when biopsies are taken

3. Currently ongoing malignancy

4. Serious concomitant inflammatory diseases and/or anti-inflammatory treatment(s) that may impair the interpretability of the protein analysis, per investigators¡¯ interpretation (e.g. microscopic colitis)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2017
Aantal proefpersonen:	92
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-05-2017
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	NL6266
NTR-old	NTR6440
Ander register	Medisch Ethische Commissie, Academisch Medisch Centrum Amsterdam : 2016_344

Resultaten