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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22599

Source
Nationaal Trial Register

Brief title
ASCERTAIN

Health condition

inflammatory bowel disease

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

To identify the source matrix that has the highest chance to yield clinically relevant IBD biomarkers in future research

To identify putative candidate biomarkers that are able to:

o differentiate between IBD and non-IBD controls

o differentiate between CD and UC

o identify subgroups within the patients groups of CD or UC in alignment with endoscopic severity.

To identify possible targets for the future development of therapeutic compounds

Study description

Background summary

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.

Study objective

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.

Study design

Cross sectional

Intervention

procurement of 5 intestinal biopsies

1 5mL serum tube withdrawal

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2017
Enrollment:	92
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6266
NTR-old	NTR6440
Other	Medisch Ethische Commissie, Academisch Medisch Centrum Amsterdam : 2016_344

Study results