ASsoCiation bEtween seRum and Tissue protein profiles in pAtients wIth iNflammatory bowel disease: the ASCERTAIN trial

Published: 09-03-2017
Last updated: 11-04-2024

1. Primary objective: 1.2 To assess the correlation of protein profiles between intestinal tissue and serum in patients with IBD2. Secondary Objectives:2.1 To identify the source matrix that has the highest chance to yield clinically relevant IBD...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON45257

Source
ToetsingOnline

Brief title
ASCERTAIN trial

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, inflammatory bowel disease, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Hoofdonderzoeker: aanwezige winstreserves

Intervention

Keyword: biomarkers, correlation, inflammatory bowel disease, proteins

Outcome measures

Primary outcome

1. Primary objective:

1.2 To assess the correlation of protein profiles between intestinal tissue and

serum in patients with IBD

Secondary outcome

2. Secondary Objectives:

2.1 To identify the source matrix that has the highest chance to yield

clinically relevant IBD biomarkers in future research

2.2 To identify putative candidate biomarkers that are able to:

2.2.1 differentiate between IBD and non-IBD controls

2.2.2 differentiate between CD and UC

2.2.3 identify subgroups within the patients groups of CD or UC in alignment

with endoscopic severity.

2.3 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

1. Primary objective:
1.2 To assess the correlation of protein profiles between intestinal tissue and serum in patients with IBD

2. Secondary Objectives:
2.1 To identify the source matrix that has the highest chance to yield clinically relevant IBD biomarkers in future research
2.2 To identify putative candidate biomarkers that are able to:
2.2.1 differentiate between IBD and non-IBD controls
2.2.2 differentiate between CD and UC
2.2.3 identify subgroups within the patients groups of CD or UC in alignment with endoscopic severity.
2.3 To identify possible targets for the future development of therapeutic compounds

Study design

Prospective multi-centre cross-sectional study

This trial will consist of two phases:

1. Prospective inclusion of 80 IBD patients (40 CD and 40 UC) with active disease and 12 non-IBD patients.

1.1 Collection of 1 serum tube (5mL) prior to endoscopy
1.2 Collection of 5 mucosal biopsies of diseased gastrointestinal tissue

2. Analysis phase:
2.1 Utilising OLINK bioscience *Proseek Multiplex Inflammation Panel*, both the serum and intestinal tissue protein profile will be defined.
2.2 Assess the correlation between the protein profiles of the intestinal tissue and the serum

Study burden and risks

This is a cross-sectional trial comprising only one time point of intervention. The burden and risks for patients are negligible. Briefly, 5 mL of blood will be drawn prior to start of endoscopy. No phlebotomy is needed as an intravenous line is already in place for medication administration. Five endoscopic biopsies are taken during endoscopy which include a minimal risk of complications, mainly bleeding or perforation (<1:10,000) [1]. In case a complication occurs, endoscopic treatment (hemostasis/clipping) is effective in most cases. Rarely, hospital admission with/without surgical intervention, antibiotic therapy and/or blood transfusion can be required.

1. Yao, M.D., et al., Multiple endoscopic biopsies in research subjects: safety results from a National Institutes of Health series. Gastrointest Endosc, 2009. 69(4): p. 906-10.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria:
1. Patients * 18 years
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 an endoscopy (ileo-, colonoscopy, sigmoidoscopy), independent of this study
5. Active disease, defined by either clinical or biochemical and endoscopic signs:
5.1 Clinical OR biochemical:
5.1.1 Clinical: CD: Harvey Bradshaw index (HBI) > 4. UC: simple clinical colitis activity index (SCCAI) * 5.
5.1.2 Biochemical: CRP > 5 mg/L or fecal calprotectin (FC) > 250 mcg/g).
AND
5.2 Endoscopic signs of active disease: CD: * 1 ulcer * 0.5 cm. UC: Mayo score * 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:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-04-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	09-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL60058.018.16