Validation of biomarkers for Crohn*s disease using peripheral blood cells of patients

Published: 04-01-2019 Last updated: 11-04-2024

The aim of the project is to validate biomarkers for the development of a peripheral blood test which can distinguish early inflammation between various forms of IBD, with the use of novel techniques, such as mass cytometry and RNAseq.

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

Summary

ID

NL-OMON48615

Source ToetsingOnline

Brief title Validation of biomarkers for Crohn*s disease

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders

Synonym crohn's disease, Inflammatory bowel disease, ulcerative colitis

Research involving Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum Source(s) of monetary or material Support: MLDS

1 - Validation of biomarkers for Crohn*s disease using peripheral blood cells of pat ... 6-05-2025

Intervention

Keyword: Biomarkers, Crohn, IBD, ILC, Mass-cytometry, Ulcerative colitis

Outcome measures

Primary outcome

Definition of final staining panel which can allow for early inflammation

dectection as well as distinguish between various forms of IBD , using

peripheral blood samples.

Secondary outcome

- 1. Whether with this peripheral blood test a flare can be predicted
- 2. Whether this peripheral blood test can distinguish CD from UC patients.
- 3. To see how the medication of IBD patients can affect immune cell activation

markers within peripheral blood.

Study description

Background summary

Innate lymphoid cells (ILCs) are important regulators of epithelial tissue integrity during homeostasis. We have recently focused on innate lymphoid cells (ILCs) in peripheral blood. In peripheral blood of healthy individuals ILCs exhibit a resting phenotype, expressing the lymph node homing receptor CD62L, suggesting that ILCs travel through lymph nodes just like naïve T cells do. However, ILCs in peripheral blood of Crohn*s patients exhibited a strongly reduced CD62L expression. Our results led us to hypothesize that ILCs will become activated in lymph nodes that drain an inflammatory site, upon which they will lose their CD62L expression. In addition, the gut homing molecule $\alpha 4\beta 7$ was expressed on ILC present in peripheral blood of Crohn*s patients and mutually exclusive with CD62L expression, allowing their migration to the intestine. In addition, we did not observe such a consistent reduction of CD62L expression on PB ILC in patients suffering from ulcerative colitis. We hypothesize that phenotypic and functional changes in peripheral blood innate lymphoid cells will allow for early detection of disease (re)activation in IBD patients as well as distinction between various forms of IBD.

Study objective

The aim of the project is to validate biomarkers for the development of a peripheral blood test which can distinguish early inflammation between various forms of IBD, with the use of novel techniques, such as mass cytometry and RNAseq.

Study design

The proposed study is designed as an prospective observational study in the setting of the outpatient clinic of the VU medical center.

Study burden and risks

Inflammatory bowel disease has been diagnosed in 9 out of 1000 citizens in the Netherlands. It is a unpleasant conditions which results in diarrhoea, pain in the abdominal region and discomfort. For this study, liquid biopsies are needed. The low risks for individual participating patients are insignificant to the knowledge that can be provided by this study. The project is aimed at improving the early diagnosis of IBD patients. By the combination of two novel techniques, much information can be obtained from very limited amount of peripheral blood. By analysing enough patients the obtained data will allow a better insight in the different subgroups within all Crohn*s and Ulcerative colitis patients. Improving the diagnosis of IBD patients, which will reduce the burden on family as well as on society.

Contacts

Public Vrije Universiteit Medisch Centrum

De Boelelaan 1108 Amsterdam 1081 HZ NL **Scientific** Vrije Universiteit Medisch Centrum

De Boelelaan 1108 Amsterdam 1081 HZ NL

3 - Validation of biomarkers for Crohn*s disease using peripheral blood cells of pat ... 6-05-2025

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Patients:

- Provide informed consent
- Within age 18 until 75
- Diagnosed with Crohn*s disease or ulcerative Colitis
- Healthy volunteers:
- Provide informed consent
- Within age 18 until 75
- Healthy, without a medical history of any inflammatory disease

Exclusion criteria

-Patients:

- Younger than 18 and older than 75
- Patients who cannot be properly informed about the risks due to an insufficient ability to speak Dutch or English
- History of another inflammatory diseaseHealthy volunteer:
- History of any inflammatory disease
- Younger than 18 and older than 75
- Employees of the department of Gastroenterology
- Family or friends of employees of the department of Gastroenterology

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	28-10-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO	
Date:	04-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	20-08-2019
Application type:	Amendment
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

ССМО

ID NL65801.029.18