

Detailed immunotyping of immune-mediated inflammatory diseases (IMIDs) by investigating cellular and molecular biomarkers in blood and synovial fluid

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The goal of this study is to identify and validate recently discovered and novel biomarkers of pathophysiology, diagnosis, classification, disease activity, prognosis, treatment susceptibility, and treatment efficacy in IMIDs.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON55821

Source

ToetsingOnline

Brief title

Immunotyping of IMIDs in blood and synovial fluid

Condition

- Autoimmune disorders
- Joint disorders

Synonym

arthritis, systemic inflammatory diseases

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: collectebusfondsen

Intervention

Keyword: biomarkers, blood, synovial fluid

Outcome measures

Primary outcome

To identify immunological alterations in the PB and SF of patients with various forms of established or early forms of immune-mediated inflammatory diseases and to correlate these alterations with diagnosis, disease stage, prognosis, and treatment response and compare this to healthy controls. We thereby aim to identify and validate novel biomarkers that can be used for personalized medicine in IMIDs

Secondary outcome

n.a.

Study description

Background summary

Despite the impact of immune-mediated inflammatory diseases, the cellular and molecular pathways (the immunotype) driving these diseases remain largely unknown. Accordingly, it remains difficult to correctly diagnose and classify these diseases at an early stage and to predict the persistence and evolution of the disease in an individual patient. Moreover, despite the development of a variety of novel and powerful drugs (including the so-called biologicals), the patient's response to treatment remains heterogeneous and difficult to predict. Therefore, there is a clear need for the identification and validation of cellular and molecular biomarkers which directly reflect the immunotype of a given disease and can provide useful clinical information for diagnosis, classification, prognosis and treatment, as well as the development of new

(preventive) therapeutic strategies.

Study objective

The goal of this study is to identify and validate recently discovered and novel biomarkers of pathophysiology, diagnosis, classification, disease activity, prognosis, treatment susceptibility, and treatment efficacy in IMIDs.

Study design

A monocenter study will be started in patients with IMIDs. Patients will be recruited from the outpatient clinic in AMC. It concerns a single visit study. Demographic data and clinical data regarding classification of diagnosis, medication use and disease activity will be collected. Once the patient has given informed consent, the synovial fluid (if obtained by the treating physician in case of standard care) will be collected and blood will be drawn for the study and if necessary for care.

Study burden and risks

Blood drawing has no additional risks except for development of a hematoma. (Synovial fluid aspiration is performed by the treating physician as a regular treatment or diagnostic tool for arthritis, therefore no additional risks are involved by participating in this study.)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- patients with clinically suspected arthralgia or a diagnosis of an immune-mediated inflammatory disease
- patients must be 18 years or older

Exclusion criteria

- patients unable to give informed consent

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	14-02-2019
Enrollment:	700

Type:

Actual

Ethics review

Approved WMO

Date:

13-04-2018

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

NL65076.018.18