Immunotyping inflammatory arthritis: Blood and synovial fluid cellular and molecular biomarkers in immune-mediated inflammatory diseases

Published: 20-06-2013
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The goals 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	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON47311

Source
ToetsingOnline

Brief title
Immunotyping inflammatory arthritis

Condition

- Autoimmune disorders
- Joint disorders

Synonym
arthritis, inflammatory systemic 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

is to identify immunological alterations in the PB and SF of patients with

various forms of inflammatory arthritis and systemic inflammatory diseases and

to correlate these alterations with diagnosis, disease stage, prognosis, and

treatment response. We thereby aim to identify and validate novel biomarkers

that can be used fro personalized medicine in IMIDs

Secondary outcome

N.A.

Study description

Background summary

Despite the impact of the 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 reflect directly 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 therapeutic strategies.

Study objective

The goals 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 multicenter study will be started in patients with IMIDs. Patients will be recruited from the outpatient clinic in AMC, Reade, Flevo and Slotervaart hopsital and concerns a single visit study. Demographic data and clinical data regarding classification of diagnosis, medication use and disease activity will be collected. The synovial fluid will be collected and blood will be drawn once the patient has given informed consent.

Study burden and risks

Blood drawing has no risks except for hematomas.
Synovial fluid aspiration is done as a regular treatment for arthritis and therefore no extra risks are involved for this research.

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 an immune-mediated disease (e.g. systemic lupus, rheumatoid arthritis, gout)
- patients of at least 18 years old

Exclusion criteria

- patients who are unable to give informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-07-2013
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO

Date:	20-06-2013

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-03-2018
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	ID
Other	MEC 03/123, geen ABR nr aanwezig, gestart in 2003
CCMO	NL44031.018.13