

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

Published: 20-06-2013

Last updated: 25-04-2024

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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Autoimmune disorders
<b>Study type</b>	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 for 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 hospital 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

### 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

- 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