# A systems biology approach to identify novel biomarkers and causative pathways in patients with psoriatic arthritis

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Autoimmune disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON45190

**Source**
ToetsingOnline

**Brief title**
From psoriasis to arthritis

### Condition

- Autoimmune disorders
- Synovial and bursal disorders
- Epidermal and dermal conditions

**Synonym**
psoriatic arthritis

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** UMC Utrecht
**Source(s) of monetary or material Support:** Pfizer,unrestricted educational grant van Pfizer.

## Intervention

**Keyword:** autophagy, biomarkers, psoriatic arthritis, systems biology

## Outcome measures

### Primary outcome

Clinical endpoints: Diagnosis (conform CASPAR criteria), disease activity and

treatment response (conform the composite scores DAS28, ACR, and CPDAI). For

details see section 8.1.1. of the study protocol.

Laboratory endpoints: the transcriptome (RNA sequencing), the epigenome (micro

RNA profiling and genome-wide methylation) and the proteome in white blood

cells derived from the blood samples collected throughout follow-up. The

frequency, phenotype, and function of the white blood cells will be

quantified. For details see section 8.2.1. and 8.4.7 of the study protocol.

### Secondary outcome

n.a.

# Study description

### Background summary

Psoriatic arthritis (PsA) is currently underdiagnosed and often resistant to treatment with traditional anti-rheumatic drugs, leading to increased morbidity and mortality. The pathogenesis of PsA is not fully understood but thought to arise from the combination of genetic, epigenetic, and environmental factors.

The so-called *systems biology approach* uses high through-put technologies to help unravel the complex interactions between such factors in order to better understand the specific pathways leading to a state of disease.

## Study objective

The primary objective is to identify molecular signatures that can serve as diagnostic and/or severity-of-disease markers for PsA and markers that can predict treatment response in patients with PsA. The secondary objective is to elucidate the underlying pathways in the development of PsA with the aim of uncovering novel therapeutic targets.

## Study design

Longitudinal observational study, where blood samples and clinical parameters will be prospectively collected for a maximum duration of five years per patient, and the data will be analysed using the systems biology approach.

## Study burden and risks

The burden of participation relies mainly on extra blood draws and filling in the questionnaires. Apart from possible small side effects of additional blood being drawn (small hematoma), no risks are involved.

Study participants with a diagnosis of psoriasis (population 1) will be clinically evaluated by a rheumatologist at baseline for the presence of PsA and will be asked to perform one blood sample at baseline (80 mL blood volume), and be asked to perform PsA-screening questionnaires once per year during follow-up.

Study participants with a diagnosis of PsA (population 2 & 3) will be asked to undergo a minimum of one blood sample per year and maximum of three blood samples per year (80 mL blood volume each time). This blood draw will coincide with a blood draw that is necessary for clinical purposes and will be randomly selected. Participants will receive questionnaires at the same time points of the blood draw.

Study participants with a diagnosis of non-PsA spondyloarthritis (population 4) will have one study blood sample drawn (80 mL bloodvolume) at the same time that standard care bloodwork is performed. Participants will receive questionnaires at the same time points of the blood draw.

The benefit for the psoriasis patient is an early diagnosis of PsA. No other benefits is expected from participation.

# 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 psoriasis, psoriatic arthritis, ankylosing spondylitis (AS), inflammatory bowel disease associated arthritis, reactive arthritis, or undifferentiated spondyloarthritis.

## Exclusion criteria

-age 17 years or younger
- age 76 years or older
-The patient has an alternative inflammatory rheumatological diagnosis (e.g. rheumatoid arthritis, gout, pseudogout).

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 02-10-2014 |
| Enrollment: | 900 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 14-05-2014 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 01-08-2016 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 | NL46903.041.13 |