

# MRI of arthralgic hands and feet of ACPA+ patients without clinical synovitis

Published: 27-04-2011

Last updated: 27-04-2024

To evaluate the presence of subclinical inflammation in painful joints in ACPA+ patients without clinical synovitis using MRI

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON36132

### Source

ToetsingOnline

### Brief title

MRI of arthralgic hands and feet of ACPA+ patients

### Condition

- Joint disorders

### Synonym

RA, Rheumatoid arthritis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Center for Translational Molecular Medicine (CTMM)

## Intervention

**Keyword:** ACPA, Arthralgia, MRI, Rheumatoid arthritis

## Outcome measures

### Primary outcome

The presence of synovitis, erosions, bone marrow edema or tenosynovitis on MRI.

### Secondary outcome

na

## Study description

### Background summary

Anti-citrullinated protein antibodies (ACPA) are autoantibodies that are frequently detected in the blood of rheumatoid arthritis patients. ACPA positive RA patients have a worse prognosis than ACPA negative patients. Several recent studies revealed that ACPA are present years before the onset of clinically detectable synovitis and that the ACPA-response matures in the preclinical phase. Our hypothesis is that ACPA-positive patients with joint complaints but without clinically detectable synovitis will have subclinical inflammation, which can be visualized by MRI.

### Study objective

To evaluate the presence of subclinical inflammation in painful joints in ACPA+ patients without clinical synovitis using MRI

### Study design

The study is a single center observational study. Patients will be scanned on the 1.5T extremity MRI. Depending on symptoms one hand or feet will be scanned. Radiographs of the hand and feet will be performed before MRI imaging as part of standard clinical practice. Standard clinical MRI protocols for the affected joint will be used. Image sequences used are T1 weighted, T2 weighted with fat suppression and T1 weighted after gadolinium contrast injection with fat suppression. MRI images will be evaluated for synovitis, tenosynovitis, erosions, bone marrow edema and cartilage damage. MRI images will be evaluated in consensus by two musculoskeletal radiologists of the LUMC who will be blinded to the patients\* names. Previously scanned images from ACPA+ RA

patients will be used for comparison.

### **Study burden and risks**

Risk: Gadolinium contrast administration: low (<1%) risk of mild reactions to administration.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Joint pain > 6 weeks (without clinical active arthritis/enthesitis)

ACPA positive

Age > 18 years

Written informed consent

## Exclusion criteria

An explanation for peripheral joint pain on plain film

Arthritis and/or enthesitis of the affected joint (physical examination within 1 week before MRI by rheumatologist)

Known painful condition, which could interfere with the evaluation of pain severity e.g. fibromyalgia

Routine MRI-contraindications (e.g. instable metal implants, pacemaker/ICD, vascular clips).

Pregnancy

## 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): 13-05-2011

Enrollment: 15

Type: Actual

## Ethics review

Approved WMO

Date: 27-04-2011

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL35400.058.11