

# Sonographic evaluation of hands, shoulders and feet in patients presenting with inflammatory pain to identify subclinical arthritis

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In this study we will evaluate the diagnostic value of ultrasound in patients presenting without clinical observable synovitis at firstconsultation compared to de clinical diagnosis by the rheumatologist in the 12 month follow-up of this study.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Synovial and bursal disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON39095

### Source

ToetsingOnline

### Brief title

SONAR

### Condition

- Synovial and bursal disorders

### Synonym

inflammatory arthritis, rheumatic diseases

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** farmaceut,Pfizer

## Intervention

**Keyword:** diagnosis, early arthritis, musculoskeletal disorders, sonografie

## Outcome measures

### Primary outcome

clinically observable arthritis by the rheumatologist within 12 months of

baseline measurement

### Secondary outcome

NA

## Study description

### Background summary

Still 5% to 25% of the patients with rheumatoid arthritis present with joint erosions at first consultation despite the early referral facilities available nowadays. To improve patients outcomes we need to identify patients before the joint damage occurs. The Rotterdam Early Arthritis Cohort criteria improved early identification of patients without synovitis who developed later on arthritis, but the numbers needed to screen are high. The screening of 20 patients identified 3 patient who later on developed arthritis.

### Study objective

In this study we will evaluate the diagnostic value of ultrasound in patients presenting without clinical observable synovitis at first consultation compared to de clinical diagnosis by the rheumatologist in the 12 month follow-up of this study.

### Study design

diagnostic design using a prospective cohort

## Study burden and risks

The study will cost approximately 3 quarters of an hour extra time to scan the hands, feet and shoulders with sonographie. Sonographie is a save method to image the inside of the body by using sound waves. There are no known side effects of this technique.

## Contacts

### Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

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Rotterdam 3000 CA  
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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

inflammatory joint complaints of hand, foot or shoulder and in addition 1 other painful joint.

## Exclusion criteria

Symptom duration > 12 months

Symptoms caused by:

Fibromyalgia

osteoarthritis

overuse

trauma

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-06-2011

Enrollment: 200

Type: Actual

## Ethics review

Approved WMO

Date: 10-12-2010

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 30-08-2011

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Approved WMO

Date: 11-07-2012

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 16-08-2012

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 01-11-2013

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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**

CCMO

**ID**

NL34428.078.10