

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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Synovial and bursal disorders
Study type	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

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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