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

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	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, Reumatoid 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

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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