Evaluation of the prevalence, incidence and progression of bone erosions in rheumatoid arthritis (RA) by high-resolution peripheral quantitative computer tomography (HRpQCT) compared to standard imaging techniques

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22023

Source
Nationaal Trial Register

Health condition

RA, HR-pQCT, MRI, US, RX, bone erosions

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Pfizer

Intervention

Outcome measures

Primary outcome

The primary outcome of the study is 1/ cross-sectionally - the prevalence of bone erosions and 2/ longitudinally - the progression of bone erosions in the 2nd and 3rd proximal interphalangeal (PIP) joints and metacarpophalangeal (MCP) joints of the hands bilaterally in patients with RA. In healthy controls only the dominant hand will be scanned and includes also the 2nd and 3rd distal interphalangeal (DIP) joints ,using the HRpQCT (800 RA joints + 480 healthy control joints in the total study).

Secondary outcome

Secondary outcomes are the comparison of the number of joints with erosions detected by HRpQCT with 1/ the number of joints with erosions detected by X-rays, MRI and US and 2/ the number of joints with osteitis by MRI; exploring possibilities to quantify the 3-D joint space volume occupied by cartilage; and the correlation between the prevalence and progression of erosions with serum bone turnover markers.

Study description

Background summary

Evaluation of the prevalence, incidence and progression of bone erosions in rheumatoid arthritis (RA) by high-resolution peripheral quantitative computer tomography (HRpQCT) compared to standard imaging techniques

Study objective

Imaging by HR-pQCT is more precise and more sensitive than CR and MRI for demonstrating differences (from controls) and changes in 3D microarchitecture of cortical bone (number, size and location of erosions, osteophytes), trabecular bone (destruction, sclerosis, healing) and indirectly of 3D cartilage volume in-vivo of hand joints in patients with hand RA and healthy controls, both cross-sectionally and longitudinally.

Study design

First year inclusion and measurements, followed by follow-up.

Intervention

25 early and 25 late female reumatoïd arthritis patients, and 40 age matched female healthy controls will be included and studied by MRI, RX, US and HR-pQCT imaging of finger joints

(MCP, PIP, DIP).

Contacts

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Eligibility criteria

Inclusion criteria

4.2 Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

Healthy controls:

1. Not known with any form of rheumatic disease

2. Subjects who understand the conditions of the study and are willing and able to comply with the scheduled evaluations.

3. Subjects who signed the Ethics Committee approved specific Informed Consent Form prior to inclusion.

Patients with RA:

1. Patients who are diagnosed with RA, based on the universally accepted ACR/EULAR criteria.

2. Patients who understand the conditions of the study and are willing and able to comply with the scheduled evaluations.

3. Patients who signed the Ethics Committee approved specific Informed Consent Form prior to inclusion.

Exclusion criteria

A subject who meets any of the following criteria will be excluded from participation in this study:

1. Patients who underwent surgery of the hand or fingers or who are expected to need surgery of the hand in due course

2. Patients with malignancy in the last 12 months

3. Patients with a neuromuscular or neurosensory deficit which would limit the ability to assess the affected joint during the HR-pQCT evaluation.

4. Patients with known systemic or metabolic disorders leading to progressive bone deterioration such as:

a. Primary hyperthyroidism

b. Primary hyperparathyroidism

c. Chronic kidney disease with eGFR< 30 ml/min.

d. Sarcoidosis

5. Patients who, as judged by the principal investigator, are mentally incompetent or unlikely to be compliant with the follow-up evaluation schedule.

6. Patients with other rheumatic disorders involving the joints, such as osteoarthritis

7. Patients who are pregnant or willing to become pregnant or are breastfeeding.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2013
Enrollment:	90
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41257
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4392
NTR-old	NTR4523
CCMO	NL42300.068.12
OMON	NL-OMON41257

Study results