

Towards defining abnormal musculoskeletal ultrasound findings * a study on hands and feet of healthy volunteers

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To investigate if healthy subjects have US-detected features of *inflammation' in order to develop an age-matched homogenous definition of normal variants of wrist, thumb base, metacarpal phalangeal, interphalangeal and metatarsal phalangeal...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON46745

Source

ToetsingOnline

Brief title

Ultrasound findings in hands and feet of healthy volunteers/ENORM

Condition

- Joint disorders

Synonym

Normal variation of ultrasound

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: feet, finger and toe joints (MCP, hand, healthy volunteer, IP, MTP), PIP, ultrasonography

Outcome measures

Primary outcome

The presence of inflammatory US features in joints and tendons of healthy subjects

Secondary outcome

The presence of osteophytes detected by US in joints of healthy subjects.

The relationship between the presence of inflammatory US features and osteophytes detected by US

The relationship between the presence of inflammatory US features in healthy subjects and demographic characteristics (i.e. age, gender and body mass index)

Study description

Background summary

Early initiation of treatment of Rheumatoid Arthritis (RA) is beneficial as it results in less joint damage during the subsequent disease course. In order to treat patients early, RA has to be recognized early. At present, recognition is done with physical examination; joints are palpated to determine whether arthritis is present. In studies in patients with early arthritis, musculoskeletal US had an additive value to physical examination by detecting subclinical inflammation, that is also associated with progression to structural damage over time. This suggests that US is a valuable prognostic tool.

Early initiation of treatment of Rheumatoid Arthritis (RA) is beneficial as it leads to less joint damage during the disease course. Therefore, early recognition is important, preferable already in the preclinical phase of the disease.

In Studies in patients with arthralgia at risk of developing RA, high resolution imaging has shown to be capable of detecting subclinical arthritis -and also tenosynovitis- that can attribute to the early identification of patients with RA.

However, in healthy subjects, subtle inflammatory features can be present in hand and foot joints, which are not disease related. In order to be able to identify early phases of RA using imaging modalities, a reference of normal variations is necessary. For MRI these references have been described recently, but unfortunately, standard reference values for US are lacking at the moment.

Study objective

To investigate if healthy subjects have US-detected features of *inflammation' in order to develop an age-matched homogenous definition of normal variants of wrist, thumb base, metacarpal phalangeal, interphalangeal and metatarsal phalangeal joints for standard reference values.

Study design

This is a cross-sectional single centre study that will be performed by the Department of Rheumatology of the Leiden University Medical Centre. Healthy subjects (200 in total) of different age categories, without complaints of hand and feet, will be recruited. An US examination will be performed of both hands, wrists and feet during one single study visit. The total duration of the study will be approximately 12-24 months.

Study burden and risks

Healthy volunteers are requested to come to the hospital for the study visit. The study visit lasts for approximately 50-60 minutes.

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

- * Age ≥ 18 years
- * No previous prolonged and/or current symptoms of wrist, thumb base, metacarpal, interphalangeal and metatarsal joints
- * Written informed consent

Exclusion criteria

- * No written informed consent
- * Previous/current inflammatory joint disease (including crystal arthropathy).
- * Visual analogue score (VAS) for current joint pain > 10/100.
- * Any history of joint trauma in the last month.
- * Fulfilling hand osteoarthritis according to the American College of Rheumatology clinical classification criteria.
- * Any clinical joint inflammation, suggestive of inflammatory rheumatic disease, as identified by a physician.
- * Previous or current inflammatory bowel disease.
- * History of culture-proven enteric and/or genitourinary infection in the last month (assessed at history taking).
- * Current or previous corticosteroids use in the last 4 weeks.
- * Current non-steroidal anti-inflammatory drugs (NSAID) use (<7 days).

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 16-05-2019

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 24-05-2018

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 10-01-2019

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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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	NL63182.058.17