Pilot study: feasibility of visualizing osteochondral defects with ultrasound in the ankle.*

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The aim of this study is to determine the sensitivity of ultrasound in diagnosing the presence of an OCD in the ankle joint at locations that can be visualized compared to CT.

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

Summary

ID

NL-OMON35632

Source
ToetsingOnline

Brief title
Ultrasound of cartilage defects

Condition

- Joint disorders

Synonym
cartilage defects; articular degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,STW beurs

Intervention

Keyword: ankle, osteochondral defect, ultrasound

Outcome measures

Primary outcome

- presence or absence of a OCD on ultrasound

- presence or absence of a OCD on CT

Secondary outcome

- size of the lesion

- location of the lesion

- Berndt and Harty classification of the lesion

Study description

Background summary

Osteochondral defects usually occur after a traumatic event. Diagnosis takes place with MRI- or CT-scan, as radiographs are unsuitable. Bone marrow stimulation is the first-line treatment option where loose cartilage pieces are removed and holes are drilled in the underlying bone which stimulates an intrinsic healing process. Although the treatment is quite successful, the results are fair to poor for about 10% of the patients. This can only be partially explained by factors such as defect size. Additionally, little is known about the true nature of the healing process. So, there is a need for in vivo monitoring to optimize this treatment. CT is unsuitable due to its ionizing radiation, and MRI is expensive and time consuming. Recently, ultrasound proposed as a means to visualize cartilage surfaces and detect small bony lesions. Although ultrasound can not reach all locations in a joint, it is noninvasive, dynamic and cheap to apply.

Study objective

The aim of this study is to determine the sensitivity of ultrasound in diagnosing the presence of an OCD in the ankle joint at locations that can be visualized compared to CT.

Study design

In total, 20 patients with a confirmed OCD on CT in ankle joint are recruited. Patients should be older than 18 years and competent. An independent physician will perform an independent diagnosis with ultrasound. The ultrasound images are recorded simultaneously with the tracking data of the position of the probe. This allows mapping of the ultrasound to CT-data. A second independent physician performs diagnosis based on the CT-data as part of the routine protocol.

Study burden and risks

No interventions will take place. Besides filling out the informed consent and a questionnaire, diagnosis with ultrasound is performed twice. There are no risks for the patients. Based on the results, it is decided if ultrasound is a good research tool for longitudinal in vivo monitoring of the healing process of osteochondral defects. This can possibly lead to improved surgical treatment and early detection of osteochondral defects.

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

- Patients should have an age 18 years or older
- Patients should be able to read the patient information
- Patients who have received a routine CT-scan of the ankle which shows an OCD of the ankle and were either treated conservatively or are on the waiting list to receive any type of surgical treatment for the confirmed OCD.

Exclusion criteria

- Patients with suspected multiple pathologies in the ankle joint
- Patients that did not receive a CT-scan
- Patients with age lower than 18 years
- Patients who are pregnant
- Patients who have not signed the informed consent form
- Patients with a previous surgical history of OCD in the ankle.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2012
Enrollment:	20

Type:	Actual

Ethics review

Approved WMO Date:	06-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL37854.018.11