Post-operative longitudinal monitoring of osteochondral defects of the talus with ultrasound after bone marrow stimulation.

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The aim of this study is to visualize and to quantitatively document the regeneration process of osteochondral defects in the human ankle following bone marrow stimulation by longitudinal monitoring at short intervals in time with ultrasound.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON45273

Source
ToetsingOnline

Brief title
Monitoring of talar OCD with US after BMS

Condition

- Bone and joint therapeutic procedures

Synonym
osteochondral defect / cartilage defect

Research involving
Human

Sponsors and support

Primary sponsor: Orthopedie

Source(s) of monetary or material Support: nvt

Intervention

Keyword: bone marrow stimulation, osteochondral defects, ultrasound

Outcome measures

Primary outcome

-Degree of filling of the osteochondral defect over time.

-Type and degree of irregularity of cartilage surface

-Loomer/Berndt and Harty classification of the lesion (pre-op)

-ICRS Cartilage Repair Assessment system

-ICRS Grade

-Location of the lesion in relation to possible visualisation with ultrasound

-Description of characteristic signs of an OCD as visualized by ultrasound at

all sample events

Secondary outcome

N.A.

Study description

Background summary

The separation of a fragment of cartilage and its subchondral bone in a joint is named an osteochondral defect (OCD). OCDs are mostly caused by a traumatic event and can involve all joints, but in practice the knee, the ankle and the elbow are most frequently damaged1-3. These OCDs cause impairment because of deep joint pain and may contribute to premature development of osteoarthritis3-5. The latter is a major cause of disability and represents a high socioeconomic burden to society.

Diagnosis takes place with MRI- or CT-scan. Bone marrow stimulation is the first-line treatment option where loose cartilage pieces are removed and holes

are drilled in the underlying bone to stimulate 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 in vivo in patients. So, there is a need for in vivo monitoring of the regeneration to optimize treatment of osteochondral defects. A previous pilot patient study showed that ultrasound can visualize OCDs in the anterior part of the talar dome. Ultrasound is desired as monitoring tool because it is truly noninvasive and relatively cheap, which allows an increased sample frequency to monitor in vivo cartilage regeneration.

Study objective

The aim of this study is to visualize and to quantitatively document the regeneration process of osteochondral defects in the human ankle following bone marrow stimulation by longitudinal monitoring at short intervals in time with ultrasound.

Study design

In total, 5 patients with a CT confirmed anterior OCD of the talus (Berndt-Hardy-Loomer grade II-V) are recruited. Patients should be older than 18 years, competent and scheduled for a BMS treatment of the OCD. Preoperatively, a 3D ultrasound sweep will be acquired to collect a 3D volume of the entire visible talar surface including the OCD. Postoperatively the patients are imaged with the 3D ultrasound sweep executed at 2, 3, 4, 5 and 6 weeks. After that there will be an ultrasound at 8, 10 and 12 weeks. Furthermore, 2 more echo sweeps will take place at 6 months and one year at regular follow up appointments. These 3D ultrasound volumes will all be registered to MRI- or CT-data as part of the routine diagnostic protocol, which serve as reference. A routine control CT scan will also be performed at one year.

Study burden and risks

Patients that participate in the study could benefit from the additional imaging with ultrasound as it might assist in achieving adequate diagnosis. As ultrasound is a truly noninvasive imaging modality, no additional risks or complications are expected. The disadvantage for patients is that they have to be present longer than the time scheduled for a follow up appointment to execute the ultrasound. This will take approximately 30 minutes per ultrasound sweep. Next to the standard care appointments there will also be 6 additional appointments for an ultrasound sweep. In total, patients will undergo 11 ultrasound sweeps. This correlates with 5 * hours of additional time needed divided over a period of 12 months.

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 or are scheduled for a routine CT-scan of the ankle which shows an OCD of the ankle and are on the waiting list to receive bone marrow stimulation treatment surgical for the OCD
-OCDs grade II-V according to the Berndt-Hardy-Loomer classification located at the anterior section of the talar dome.

Exclusion criteria

-Patients with suspected multiple pathologies in the ankle joint

-Patients that are not able to or did not receive a CT-scan
-Patients younger than 18 years
-Patients who have not signed the informed consent form

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	5
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-02-2017
Application type:	First submission
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	NL60518.018.17