Feasibility study for MR Imaging Osteochondral Defects of the Talus using T1rho imaging

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Primary Objective: Validation of T1rho&T2mapping in healthy volunteers and patients with an OCD of the talusSecondary objective: To quantify T1rho & T2 mapping in patients with osteochondrial defects against healthy volunteers with 3T MRI...

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

Summary

ID

NL-OMON49606

Source
ToetsingOnline

Brief title
T1rho for talar OCD

Condition

- Joint disorders

Synonym
anklejoint damage, Osteochondral lesions

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ankle, Compositional MRI, Osteochondral Defects, Talus

Outcome measures

Primary outcome

Primary outcomes are the T1rho relaxation times of healthy volunteers and

patients at two different spinlock frequencies.

Secondary outcome

Secondary outcomes are the T2 relaxation times of healthy and patients and

correlate these times to the T1rho times for complementary

Study description

Background summary

Osteochondral defects (OCD) of the talus are common injuries of the ankle. This injury is mostly caused by a single or multiple trauma to the ankle and can cause deep ankle pain during weight bearing movements. If the defect remains untreated, further deterioration of the joint can occur and even osteoarthritis of the ankle. Often surgery is needed to relieve of symptoms.
Current diagnosis en preoperative planning consists of radiography, MRI and CT. To acquire a better picture of the extent of cartilage damage, various techniques exist to assess the compositional or biochemical properties of the cartilage tissue with MRI. One of these techniques is T1rho. This technique has shown to be sensitive for glycosaminoglycans and proteoglycans content. Previous research with T1rho have been done for applications in the knee for osteoarthritis and cartilage repair with promising results. Another similar technique will also be investigated, namely T2, this has shown to be more specific for collagen content and orientation. The application of T1rho has not yet been investigated in the ankle and this study shall research the feasiblity of T1rho for identifying and quantifying cartilage damage in the ankle.

Study objective

Primary Objective: Validation of T1rho&T2mapping in healthy volunteers and patients with an OCD of the talus

Secondary objective: To quantify T1rho & T2 mapping in patients with osteochondrial defects against healthy volunteers with 3T MRI based on talus cartilage.
Tertiary objective: To gain insight into the clinical application of T1rho and T2 for identifying and quantifying cartilage damage.

Study design

Patients with an osteochondral defect of the ankle will be asked preoperatively to participate in the study. healthy volunteers will be recruited through a pamphlet. There will be no follow-up.
Within 19 months we expect to have recruited and scanned the subjects as well as analyzed the obtained data.

Study burden and risks

Risks for the subjects undergoing a MRI examination are minimal, provided precautions have been made to prevent examining individuals with contraindications. For this purpose, the routine MRI contra indications form of the AMC will be used. There is no direct group related benefit.

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

informed consent, no ankle pain (healthy), diagnosed OCD (patient), BMI under 30,

Exclusion criteria

suspicion of pregnancy, metallic objects inside subject body (like pacemakers)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-10-2016
Enrollment:	62
Type:	Actual

Medical products/devices used

Generic name:	T1rho software patch

Registration:	No

Ethics review

Approved WMO Date:	03-11-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2019
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	NL59024.018.16