PEMF after Ankle Arthroscopy for ODs of the Talus.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21060

Source
Nationaal Trial Register

Brief title
PEMF-trial

Health condition

Osteochondral defect, Osteochondral lesion, Ankle, Talus, Arthroscopy
Osteochondraal defect, Osteochondritis dissecans, Enkel, Talus, Artroscopie

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: Stryker

Intervention

Outcome measures

Primary outcome

The combined primary outcome measures are:

1. The number of patients that resume and maintain sports during 12 months follow-up;

2. The time to resumption of sports, defined by the AAS.

Secondary outcome

1. Time to resumption of work;

2. American Orthopaedic Foot and Ankle Society - Ankle and Hindfoot clinical rating System (AOFAS-AHS);

3. Foot and Ankle Outcome Score (FAOS);

4. Quality of life (EuroQol);

5. Pain;

6. Satisfaction;

7. Computed tomography evaluation;

8. Adverse events.

Study description

Background summary

Background:

Pulsed Electromagnetic Fields (PEMF) have been used since three decades. In animal research the effect on cartilage and bone regeneration has been proven. Clinically, however, the only entities on which an effect is objectified are delayed union or nonunion of bone fractures and knee arthroscopy; clinical results of PEMF as a solitary treatment for osteoarthritis are conflicting in different studies. In view of the working mechanism of PEMF we expect a positive effective of the treatment on osteochondral ankle defects after arthroscopic treatment.

Objective:

To achieve earlier sport resumption in more patients due to PEMFs compared to placebo.

Study design:

A double-blind, randomized, placebo controlled multicenter trial

Study population:

Active patients aged 18 years or older who receive arthroscopic treatment for an osteochondral ankle defect.

Intervention:

During 60 days after surgery patients will receive a device around the ankle (4 hrs/d) which produces electromagnetic fields or sham device.

Primary study parameters/outcome of the study:

Combination of timing of resumption of sports (weeks after surgery) and number of patients that resume sports.

Secundary study parameters/outcome of the study:

1. Work resumption;

2. AOFAS-AHS: American Orthopaedic Foot and Ankle Society;

3. Ankle Hindfoot Scale;

4. FAOS: Foot and Ankle Outcome Score;

5. Quality of life (EQ-5D);

6. Pain and satisfaction on a Visual Analogue Scale;

7. Bone regeneration on CT;

8. Side-effects.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

In former studies with PEMF no serious side-effects have been reported. The treatment will take place in a similar manner (frequency and duration) as in one of these studies. If a complaint or side-effect should occur, participating patients will have the opportunity to stop with the study at all times.
The treatment with PEMFs is noninvasive and is relatively simple to implement in the rehabilitation period of the current standard treatment of osteochondral defects. Patients will not feel the electromagnetic fields, nor will they hear the device, and the risk of side-effects is minimal. There will be no extra visits to the hospital. However, the visits will be longer than

usual because of the assessment of research outcome (max. 30 min). Next to this, the patients will be contacted by telephone twice. The additional CT-scan involves exposure to radiation.

Study objective

We hypothesize that PEMF-treatment will be of additional value after the primary arthroscopic treatment of an OD, and the resumption of sports can be both improved and accelerated.

Study design

1. Baseline (preoperative);

2. 1-2 weeks postop;

3. 1 month postop;

4. 2 months postop;

5. 6 months postop;

6. 1 year postop.

Intervention

In both groups the investigational treatment (active PEMF-treatment or sham device treatment) will start three days after surgery. It will be applied four hours daily (in one or two sessions) for a period of 60 days .

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with a symptomatic OD of the talus who are scheduled for arthroscopic debridement and microfracture;

2. OD diameter < 15 mm on computed tomography;

3. Ankle Activity Score (AAS) >= 4 before symptoms;

4. Age 18 years or older.

Exclusion criteria

1. Concomitant OD of the tibia;

2. Ankle osteoarthritis grade 2 or 3;

3. Ankle fracture < 6 months before scheduled arthroscopy;

4. Surgical treatment of the index ankle performed < 1 year before scheduled arthroscopy;

5. Concomitant painful or disabling disease of the lower limb;

6. Rheumatoid arthritis;

7. Pregnancy;

8. Implanted pacemaker;

9. Participation in concurrent trials;

10. Participation in previous trials < 1 year, in which the subject has been exposed to radiation (radiographs or CT);

11. Patients who are unable to fill out questionnaires and cannot have them filled out;

12. No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-02-2009
Enrollment:	68
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-01-2009
Application type:	First submission

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
NTR-new	NL1557
NTR-old	NTR1636
Other	NL/MEC AMC : 19129.018.08/ 08/326
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A