PEMF after Ankle Arthroscopy for ODs of the Talus.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21060

Bron
NTR

Verkorte titel
PEMF-trial

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Stryker

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Baseline (preoperative);

2. 1-2 weeks postop;

3. 1 month postop;

4. 2 months postop;

5. 6 months postop;

6. 1 year postop.

Onderzoeksproduct en/of interventie

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 .

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind

Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-02-2009
Aantal proefpersonen:	68
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-01-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1557
NTR-old	NTR1636
Ander register	NL/MEC AMC : 19129.018.08/ 08/326
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A