Pulsed Electromagnetic Fields after Arthroscopic Treatment for Osteochondral Defects of the Talus: Double-blind Randomized Controlled Multicenter Trial

Published: 12-12-2008
Last updated: 07-05-2024

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

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON31683

Source
ToetsingOnline

Brief title
PEMF-trial

Condition

- Joint disorders

Synonym
bone and cartilage defect, osteochondral defect

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Stryker Howmedica,Stryker Nederland

Intervention

Keyword: ankle, osteochondral defect, pulsed electromagnetic fields, randomised controlled trial

Outcome measures

Primary outcome

Combination of timing of resumption of sports (weeks after surgery) and number

of patients that resume sports.

Secondary outcome

work resumption

AOFAS-AHS: American Orthopaedic Foot and Ankle Society - Ankle Hindfoot Scale

FAOS: Foot and Ankle Outcome Score

quality of life (EQ-5D)

pain and satisfaction on a Visual Analogue Scale

bone regeneration on CT

Side-effects

Study description

Background summary

Pulsed Electromagnetic Fields (PEMF) haven 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 is 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.

Study 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

Intervention

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

Study burden and risks

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.

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

1. Patients with a symptomatic osteochondral defects of the talus who are scheduled for arthroscopic debridement and microfracturing.
2. diameter < 15 mm
3. active sporters (ankle activity score > 3)
4. 18 years or older

Exclusion criteria

Concomitant osteochondral defect of the tibia
Ankle osteoarthritis grade 2 or 3
Ankle fracture < 6 months before scheduled arthroscopy
Surgical treatment of the index ankle performed < 1 year before scheduled arthroscopy
Concomitant painful or disabling disease of the lower limb
Rheumatoid arthritis
Pregnancy
Implanted pacemaker
Participation in concurrent trials
Participation in previous trials < 1 year, in which the subject has been exposed to radiation (radiographs or CT)
Patients who are unable to fill out questionnaires and cannot have them filled out
No informed consent

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	48
Type:	Anticipated

Medical products/devices used

Generic name:	Pulsed Electromagnetic Fields
Registration:	Yes - CE intended use

Ethics review

Approved WMO

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	NL19129.018.08