weak magnetic fields against pain in fibromyalgia

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We aim to study the effects of PEMF on pain in fibromyalgia.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41810

Source
ToetsingOnline

Brief title
pemFMS

Condition

- Other condition
- Somatic symptom and related disorders

Synonym
weak parts reuma

Health condition

medisch onbegrepen klachten

Research involving
Human

Sponsors and support

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

Intervention

Keyword: fibromyalgia, neuromodulation

Outcome measures

Primary outcome

Cerebral functioning (fMRI) t rest and during a movement task

Secondary outcome

Visual Analoge Scale for pain (0-10), change in score between baseline (week 0)

and endpoint (week 5) and Fibromyalgie Score (FS) (sum WPI and SS, see

protocol, and psychological well-being (questionnaires)

Study description

Background summary

Rationale: Fibromyalgia is a common medically unexplained condition with unexplained pain as a core symptom. A novel intervention, weak TMS with pulsed electromagnetic fields, here called PEMF, was recently reported to have rapid painreducing effects. This method is easy to administer and is therefore an intresting new intervention against unexplained pain.

Study objective

We aim to study the effects of PEMF on pain in fibromyalgia.

Study design

Randomized, stratified and minimised, double-blind placebo controlled intervention study. Treatment lasts for five weeks. Measurements are made in the week preceding initiation of treatment, during the treatment period, at the end of the treatment period and five and fifteen weeks after the end of treatment.

Intervention

Intervention (if applicable): One group receives 30 minutes of PEMF treatment

per day for five days per week, for five weeks in a row (PEMF group). The other group receives placebo (SHAM group) for the same amount of time. In both groups normal treatment with medication or other forms of behavioural of physical therapy will be continued as part of standard care.

Study burden and risks

Patients visit the treatment room for five weeks. Daily visits on working days lasting one hour each. Therefore in total it takes 25 hours in the treatment room.
The treatment itself might be experienced as boring by the patients, because they have to sit still for 30 minutes. Reading is allowed to alleviate this.
No adverse events or risks due to the intervention are expected.
There are two MRI sessions, spread out over 5 weeks. Each session lasts for no longer than 60 minutes. During the scans patients lie in the MR-scanner, which is a narrow space and are required to lie still. During certain periods they perform tasks.
The questionnaires constitute a negligible to mild burden.
No other behaviours are enforced or prohibited.
Patients are allowed to continue their medication and/or psychotherapy during treatment.

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

fibromyalgia
pain

Exclusion criteria

severe psychiatric illness
neurological disorder
change in medication/ongoing therapy during study and 4 weeks before

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	weak magnetic stimulation
Registration:	No

Ethics review

Approved WMO Date:	02-10-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL50034.042.14