Neurophysiological effects of transcutaneous electrical nerve stimulation in persons with MS - a pilot study

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

Summary

ID

NL-OMON57305

Source
ToetsingOnline

Brief title
fMRI-TENS

Condition

- Demyelinating disorders

Synonym
MS, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: St De Cock-Hadders

Intervention

Keyword: fMRI, Multiple Sclerosis, Transcutaneous Electrical Nerve Stimulation

Outcome measures

Primary outcome

Blood-oxygen-level-dependent (BOLD) activation changes and the interaction networks before, during and after active TENS and differences in activation due to active stimulation vs. sham stimulation and active stimulation on tibialis anterior vs active stimulation combined with plantar/dorsiflexion.

Secondary outcome

Changes in brain activity and the interaction networks focussing on the thalamus (integration station of sensory input), sensory cortex (sensory awareness) and motor cortices (sensorimotor integration) before, during and after active stimulation of the quadriceps femoris vs. tibialis anterior, active stimulation of the tibialis anterior vs. plantar/dorsiflexion, sham stimulation of the tibialis anterior vs. sham stimulation combined with plantar/dorsiflexion and active stimulation in pwMS vs. active stimulation in controls.

Study description

Background summary

Transcutaneous Electrical Nerve Stimulation (TENS) is a new treatment that could potentially reduce walking problems and fatigue in persons with Multiple Sclerosis. However, extensive use of TENS in a clinical setting is hindered by a lack of neurophysiological understanding of the effects of TENS.

Study objective

The primary objective of this pilot study is therefore to investigate the effects of TENS on brain activity in pwMS measured with fMRI.

Study design

This study is a pilot study to see if we can detect changes in fMRI activity during TENS in persons with MS. This is a randomized, single-blind crossover design. Subjects will undergo an MRI scan while they receive sham stimulation of the tibialis anterior, active stimulation of the tibialis anterior, stimulation of the quadriceps, perform continuous movements of the foot (plantar & dorsiflexion) and a combination of stimulation of the tibialis anterior and movement of the foot.

Intervention

Active or sham TENS either in rest or in combination with foot movements.

Study burden and risks

There are no serious risks involved in the measurements nor the TENS protocol. The time investment for the subject is 1 appointment of a total 3 hours. fMRI measurements are non-invasive and non-painful. The only known risks are to individuals with cardiac pacemakers, certain types of metallic implants, and metal splinter in the eyes. Subjects will have to fill out a safety questionnaire to make sure they are not at risk. The neurophysiological effects of TENS are not known. This study can add to the limited knowledge and possibly help to personalize and implement TENS in the clinic.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- age: 18-65 years
- EDSS score < 7

Exclusion criteria

- metal or electrical implants
- BMI > 40
- claustrophobia
- being pregnant
- having a psychiatric disorder
- having cognitive or communication problems which reduces the capacity to understand instructions
- having a neurological disorder other than MS
- having cardiac arrhythmia
- having a pacemaker or another implantable electronic apparatus.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2025
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	14-01-2025
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	NL86181.042.24