Reigniting the little brain: an exploratory trial of cerebellar transcranial direct current stimulation in SCA3

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The primary objective of this study is:* To investigate whether a two-weeks intervention with cerebellar anodal tDCS could improve ataxia severity in SCA3 patients compared to sham stimulation.Secondary objectives of this study are:* To investigate...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON46775

Source
ToetsingOnline

Brief title
An exploratory trial of cerebellar tDCS in SCA3

Condition

- Movement disorders (incl parkinsonism)

Synonym
Spinocerebellar ataxia type 3

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: Cerebellum, Spinocerebellar ataxia, Transcranial direct current stimulation

Outcome measures

Primary outcome

The primary outcome measure is the absolute change on the Scale for the Assessment and Rating of Ataxia (SARA).

Secondary outcome

Secondary outcome measures include SCA Functional Index (motor performance), Inventory of Non-Ataxia Signs count (extracerebellar involvement), EQ-5d (quality of life), Patient Health Questionnaire-9 (depression), short version of the POMS (mood states), Cerebellar Cognitive Affective Syndrome scale (specifically cerebellar cognitive functions), Activities of Daily Living, amount of medical consumption, percentage and timing of conditioned responses using a delay eyeblink classical conditioning (EBCC) paradigm (motor learning), and cerebellar brain inhibition using transcranial magnetic stimulation (TMS).

Study description

Background summary

Spinocerebellar ataxia type 3 (SCA3) is the most common subtype among the autosomal dominant cerebellar ataxias, a group of debilitating, progressive conditions for which currently no disease-specific treatment * i.e. aimed at the underlying molecular and cellular processes * is available. Evidence-based options for symptomatic treatment of ataxia are also limited. Recent investigations in a heterogeneous group of both hereditary and acquired ataxias show promising results of cerebellar transcranial direct current stimulation (tDCS). We here aim to test the hypothesis that increasing cerebellar excitability through cerebellar tDCS improves ataxia symptoms in a homogeneous

cohort of SCA3 patients.

Study objective

The primary objective of this study is:
* To investigate whether a two-weeks intervention with cerebellar anodal tDCS could improve ataxia severity in SCA3 patients compared to sham stimulation.

Secondary objectives of this study are:
* To investigate whether a two-weeks treatment with cerebellar anodal tDCS could improve various non-motor symptoms in SCA3 patients compared to sham stimulation.
* To investigate whether a two-weeks treatment with cerebellar anodal tDCS in SCA3 patients enhances their ability to acquire conditioned response in a delayed eyeblink classical conditioning paradigm compared to sham stimulation.
* To investigate whether a two-weeks treatment with cerebellar anodal tDCS in SCA3 modulates cerebellar brain inhibition pathways compared to sham stimulation.

Study design

Double-blind, randomized (1:1), sham-controlled, single-center exploratory trial.

Intervention

Patients will be randomized to either real or sham cerebellar tDCS, an increasingly used, short, cheap, and non-invasive tool that modulates cerebellar excitability using a pair of electrodes.

Study burden and risks

The load on patients consists predominantly of the time spent on the project, i.e. tDCS 5 days/week for 2 consecutive weeks and the follow-up visits at 3, 6, and 12 months. Furthermore, they are asked to fill in the aforementioned questionnaires. All measurements (tDCS, TMS, and EBCC) are non-invasive and without significant side effects (*negligible risk*)

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

* A proven SCA3 mutation (ATXN3 gene).
* Age * 16 years.
* SARA score * 20 (on a scale of 0 to 40).

Exclusion criteria

* Contra-indications for tDCS, i.e. metallic implants near the electrodes or the presence of unstable medical conditions or any illness that may increase the risk of stimulation, e.g. epilepsy or eczema under the electrodes.
* Significant comorbidities that interfere with activities of daily life.
* Co-morbid neurological conditions.
* Use of neurotropic medication.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-10-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	26-06-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21004
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65454.091.18
OMON	NL-OMON21004