Treating big problems arising from the little brain: A double-blind, sham-controlled, exploratory trial to investigate the effect of cerebellar anodal transcranial direct current stimulation in patient with CCAS

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The primary objective is:To investigate whether a two-weeks intervention with cerebellar anodal tDCS could improve CCAS severity in patients with cerebellar disorders compared to sham stimulation.Secondary objectives are:• To investigate whether a...

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

Summary

ID

NL-OMON52902

Source
ToetsingOnline

Brief title
An exploratory trial of cerebellar tDCS in CCAS

Condition

- Movement disorders (incl parkinsonism)

Synonym
CCAS, cerebellar cognitive affective syndrome

Research involving

Human

Sponsors and support

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

Intervention

Keyword: CCAS, Cerebellar ataxias, Transcranial direct current stimulation

Outcome measures

Primary outcome

The change in neuropsychological performance (using a composite z-score covering relevant domains affected in CCAS) between 6 weeks post-treatment and pre-treatment, real vs. sham stimulation.

Secondary outcome

• The absolute change on the Scale for the Assessment and Rating of ataxia (SARA)

• EQ-5d

• The shortened 32-item version of the Profile of Mood States (POMS)

• Cerebellar cognitive affective/Schmahmann syndrome (CCAS) scale

• Possible tDCS-related side effects

• Percentage of patients in both conditions that correctly guess to which groups they have been randomized

• Exploratory outcomes: correlations between response to intervention and relevant patient and disease-related factors (e.g. age, stroke vs. degenerative disease).

Other study parameters:

• Age

• Gender

• Age at disease onset

• Lesion mapping on available clinical MRI (for young stroke patients)

Study description

Background summary

Cerebellar disorders are relatively frequent, with at least a couple of thousand patients in the Netherlands. These disorders do not only cause disturbed coordination (ataxia), but also lead to cognitive and affective problems that are, however, often neglected in clinical settings. The prevalence of this cerebellar cognitive affective syndrome (CCAS) is probably around 80% in patients with both static and progressive cerebellar disorders. CCAS has a huge impact and contributes significantly to the perceived impact in daily life and reduced quality of life. CCAS aries due to disturbed connections between the cerebellum and mainly frontal cortical areas involved in the regulation of cognition and emotion. Earlier studies have indicated that these functional couplings can be improved by non-invasive brain stimulation (NIBS). With this explorative trial, we here test the effect of cerebellar transcranial direct current stimulation (tDCS) on CCAS in 40 patients with cerebellar ataxias. There is an increasing interest in the application of NIBS in neurology and psychiatry, evidenced for example by the approval of NIBS as a treatment of refractory depression in the Netherlands. A positive outcome of this trial proposed here would mean that a relatively easy, quick, standardized, and low cost treatment for CCAS in patients with cerebellar ataxias would be available. Furthermore, it will stimulate further research into this intervention in other brain disorders.

Study objective

The primary objective is:
To investigate whether a two-weeks intervention with cerebellar anodal tDCS could improve CCAS severity in patients with cerebellar disorders compared to sham stimulation.

Secondary objectives are:
• To investigate whether a two-weeks treatment with cerebellar anodal tDCS

could improve motor symptoms in these patients compared to sham stimulation.
• To investigate whether a two-weeks treatment with cerebellar anodal tDCS in these patients influences mood and quality of life.
• To investigate the dynamics of a possible tDCS effect on CCAS over the course of one year.
• To explore whether certain patient characteristics modulate possible tDCS effects on CCAS.

Study design

Explorative, randomized (1:1), sham-controlled, double blind, single-center 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 10, 42, 90, 180 and 365 days. During the study visits, patients are subjected to neuropsychological tests, neurological examination and are asked to fill in the aforementioned questionnaires for quality of life and mood. The intervention (tDCS) is 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

Minimum age of 16, and:
A diagnosis of degenerative cerebellar ataxia, or:
A diagnosis of cerebellar stroke below age of 65 years, and:
CCAS, measured as impairment on a brief neuropsychological test battery (7 sets) with 3 or more tests scoring below 1.5 SD or 2 tests below 2 SD

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.
• Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	02-09-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-12-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-07-2022
Application type:	Amendment
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: 28534
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL73572.091.20