Cerebellar transcranial direct current stimulation in CCAS patients

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28534

Source NTR

Brief title CCAS-tDCS

Health condition

CCAS patients with ataxia or cerebellar stroke

Sponsors and support

Primary sponsor: Radboud University Medical Center Nijmegen **Source(s) of monetary or material Support:** Hersenstichting

Intervention

Outcome measures

Primary outcome

- Change in neuropsychological performance (a composite z-score covering relevant domains affected in CCAS, focusing on executive function and attention).

Secondary outcome

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- SARA score

- CCAS/Schmahmann scale
- EQ-5d (quality of life)
- POMS (mood)
- 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 (eg, age, stroke vs. degenerative disease).

Study description

Background summary

Rationale: 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. There is an increasing interest in the application of non-invasive brain stimulation (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 the trial proposed here would mean that this relatively easy, quick, standardized, and low-cost treatment option for these neuropsychological sequelae of cerebellar disorders should be considered to implement.

Objective: To investigate whether a two-week treatment with cerebellar anodal tDCS could improve CCAS severity compared to sham stimulation.

Study design: Double-blind, randomized (1:1), sham-controlled, single-centre exploratory trial.

Study population: 40 CCAS patients in the Netherlands.

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

Main study parameters/endpoints: The primary outcome measure is the change on a composite z-score of a combined set of neuropsychological tests that specifically capture CCAS at 6 weeks post-treatment, real versus sham. Secondary outcome measures include the Scale for the Assessment and Rating of Ataxia (SARA, ataxia severity), 32-item version of the Profile of Mood States questionnaire (POMS, mood state), EQ-5d (quality of life), and the Schmahmann scale (CCAS). Periodic and structured follow-up up to 1 year for primary and secondary outcome measures will allow us to characterize the dynamics of the treatment effect, and explore patient and disease characteristics that influence the effect.

Study objective

We aim to test the hypothesis that increasing excitability of the cerebellum – through cerebellar tDCS – improves also the non-motor features of cerebellar disorders, and more specifically CCAS, in patients with cerebellar disorders. If we are indeed able to show that cerebellar stimulation via tDCDS can improve CCAS, this would provide direct health benefits and would mean that this readily available, safe, feasible, and new tool for the management of CCAS in patients with cerebellar ataxias could be considered for further studies and first steps towards implementation.

Study design

- Pre-baseline / screening
- T0 / baseline: day 1, before intervention
- T1: day 12, after intervention
- T2: 6 weeks after baseline
- T3: 13 weeks after baseline
- T4: 26 weeks after baseline
- T5: 52 weeks after baseline

Intervention

- Target (real cerebellar tDCS): 2 mA/ active electrode over medial cerebellum (2 cm below the inion with electrode's lateral borders 1 cm medially to the mastoid apophysis: 35 cm² / current density: 0.05 mA/cm², reference electrode (right deltoid muscle): 25 cm² / current density: 0.08 mA/cm²; total duration: 20 minutes.

- Control (sham cerebellar tDCS): 2 mA/ active electrode over medial cerebellum (2 cm below the inion with electrode's lateral borders 1 cm medially to the mastoid apophysis: 35 cm² / current density: 0.05 mA/cm², reference electrode (right deltoid muscle): 25 cm² / current density: 0.08 mA/cm²; total duration: 60 seconds.

Target and control stimulation will involve a ramp-up period of 15s in which intensity is gradually increased to 2 mA.

Contacts

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Eligibility criteria

Inclusion criteria

- Age \geq 16 years

- A diagnosis of degenerative cerebellar ataxia or a diagnosis of cerebellar stroke below age 50 years

- CCAS, measured as impairment on a brief neuropsychological test battery (7 tests) 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, including cerebral lesions on MRI.
- Use of neurotropic medication.
- Pregnancy.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2020
Enrollment:	40
Туре:	Anticipated

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IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date: Application type:

14-12-2020 First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52902 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9121
ССМО	NL73572.091.20
OMON	NL-OMON52902

Study results