Cerebellar transcranial direct current stimulation in CCAS patients

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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…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28534

Bron
NTR

Verkorte titel
CCAS-tDCS

Aandoening

CCAS patients with ataxia or cerebellar stroke

Ondersteuning

Primaire sponsor: Radboud University Medical Center Nijmegen
Overige ondersteuning: Hersenstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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

Onderzoeksproduct en/of interventie

- 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 cm^2 / current density: 0.05 mA/cm^2, reference electrode (right deltoid muscle): 25 cm^2 / current density: 0.08 mA/cm^2; 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 cm^2 / current density: 0.05 mA/cm^2, reference electrode (right deltoid muscle): 25 cm^2 / current density: 0.08 mA/cm^2; 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.

Contactpersonen

Publiek

Radboud umc
Stacha Reumers

024-3098145

Wetenschappelijk

Radboud umc
Stacha Reumers

024-3098145

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2020
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-12-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52902
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten