Cerebellar transcranial direct current stimulation in SCA3

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

Samenvatting

ID

NL-OMON21004

Bron
NTR

Verkorte titel
SCA3-tDCS

Aandoening

Spinocerebellar ataxia type 3 (spinocerebellaire ataxie type 3)

Ondersteuning

Primaire sponsor: Radboud University Medical Center Nijmegen.
Overige ondersteuning: Hersenstichting (Brugling Fund).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Absolute change of the SARA score between baseline and T1.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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 ¨C i.e. aimed at the underlying molecular and cellular processes ¨C 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.

Objective: To investigate whether a two-weeks treatment with cerebellar anodal tDCS could improve ataxia severity and a variety of non-motor symptoms (including motor learning) and whether it could modulate cerebellar brain inhibition pathways compared to sham stimulation.
Study design: Double-blind, randomized (1:1), sham-controlled, single-center exploratory trial.

Study population: 20 SCA3 patients.

Intervention: Patients will be randomized to either sham or real cerebellar tDCS, an increasingly used, short, cheap, and non-invasive tool that modulates cerebellar excitability using a pair of electrodes.
Main study parameters/endpoints: The primary outcome measure is the absolute change on the Scale for the Assessment and Rating of Ataxia (SARA). 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).

Country of recruitment: the Netherlands.

Doel van het onderzoek

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 ¨C i.e. aimed at the underlying molecular and cellular processes ¨C is available. Evidence-based options for symptomatic treatment of ataxia are

also limited. Cerebellar transcranial direct current stimulation (tDCS) is an increasingly used, safe, short, cheap, and non-invasive tool that aims to modulate cerebellar excitability. Recent investigations in a heterogeneous group of both hereditary and acquired ataxias show promising results of cerebellar 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.

Onderzoeksopzet

- T0 before tDCS: baseline measurement, day 1.

- T0 after tDCS: to evaluate the effects of a single session of cerebellar tDCS, day 1.

- T1: after 10 days of cerebellar tDCS.

- T2: three months after T0.

- T3: six months after T0.

- T4: twelve months after T0.

Onderzoeksproduct en/of interventie

- Real cerebellar tDCS: anode (35 cm2) over the scalp 2 cm below the inion in the midline, cathode (35 cm2) over the right deltoid muscle. Total duration of stimulation: 20 minutes at 2 mA.
- Sham cerebellar tDCS: anode (35 cm2) over the scalp 2 cm below the inion in the midline, cathode (35 cm2) over the right deltoid muscle. Duration: 20 minutes (of which 40 seconds real stimulation, 2 mA).
Ramp-up and ramp-down periods of 30 seconds will be applied in which intensity is gradually increased to or decreased from 2 mA.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- A proven SCA3 mutation (ATXN3 gene).

- Age 16 years and older.

- SARA (Scale for the Assessment and Rating of Ataxia) score 20 or less.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Epilepsy.

- History of brain surgery.

- Co-morbid neurological conditions.

- Metallic implants in or near the skull.

- Pacemaker.

- Significant comorbidities that interfere with activities of daily life.

- Pregnancy.

- Severe skin disease affecting the location where the tDCS electrodes will be placed.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	20
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:	08-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46775
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7321
NTR-old	NTR7537
CCMO	NL65454.091.18
OMON	NL-OMON46775

Resultaten