Transcranial Alternating Current Stimulation (tACS) in Adult Classic Galactosemia

Gepubliceerd: 17-12-2019 Laatst bijgewerkt: 13-12-2022

We hypothesize that tACS can entrain oscillations in individuals with Classic Galactosemia and relevant frequencies such that they result in improvements of their motor and language performance

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20217

Bron
Nationaal Trial Register

Verkorte titel
NIBS.CG

Aandoening

Classic Galactosemia

Ondersteuning

Primaire sponsor: azM
Overige ondersteuning: Galactosemia Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

We propose a proof of concept study to apply noninvasive brain stimulation, specifically tACS, for the first time to adult CG patients with the aim to find stimulation protocols that improve their motor and language performance by positively influencing their brain oscillatory profiles. Thereby we hypothesize that tACS can entrain oscillations in individual and relevant frequencies such that they result in improvements of their motor and language performance.

Toelichting onderzoek

Achtergrond van het onderzoek

The brain is one of the major target organs affected in classic galactosemia (CG). Patients suffer from speech and motor problems among others. These problems are related to observed changes in functional and anatomical brain networks compared to healthy controls. Cognitive and motor functions are driven by neuronal oscillation in certain frequency bands, with language syllables-theta (5-8 Hz) and motor-beta (15-30Hz) rhythm. In this proof of concept study, we propose to (1) investigate for the first time which frequency bands are affected in adult CG compared to healthy controls. We also propose to (2) apply one form of non-invasive brain stimulation (NIBS), namely transcranial alternating current stimulation (tACS) which can entrain brain oscillations in individual and relevant frequencies such that they result in behavioral improvement. NIBS has shown to have therapeutic efficacy in various neurological and psychiatric disorders. It has not yet been applied in CG. TACS is our method of choice as it’s possible to change oscillations during a longer period of time, compared to TMS and tDCS.
We compare brain oscillation and tACS efficiency of CG adults and matched healthy controls. 25 participants per group will have three sessions, two with real stimulation, one with sham. Sham stimulation is used to assess the efficacy of active stimulation and placebo effects. Each session consists of three elements referred to as pre, during, and post stimulation. In the pre stimulation part of the session, we quantify behavior (speed and accuracy) and electroencephalography (EEG) oscillation profiles per individual. With regard to behavior we measure reaction times and accuracy for selected language tasks. With regard to brain oscillation, we acquire EEG at rest as well as during the execution of the active language task. For each individual, we decompose the obtained EEG signal into frequency bands and compare the frequency power spectrum of CG and healthy controls. This benchmarking procedure allows us to define “relevant frequencies”. Frequencies are “relevant” when their power clearly differ between CG and controls or when they clearly modulate during an active task. During the stimulation, participants perform the same task as in the pre session while we simultaneously apply tACS or sham in the relevant frequency and record behavioral performance. TACS should now entrain the cortical brain oscillation network relevant for that task and should lead to behavioral improvement. During post stimulation, behavior and EEG will again be quantified immediately after stimulation, again for resting state and active tasks.
To investigate whether tailored stimulation driven entrainment results in optimization of behavior we analyze tACS induced behavioral change by comparing pre, during and post tACS stimulation performance within and across groups. We also quantify tACS induced pre-

post changes in the EEG frequency power spectrum within and across groups. In addition, we correlate behavioral and EEG change to investigate their relation. The proof of concept study contributes to a first understanding of brain oscillation in CG and to tACS as treatment in CG. The proposed research requires and provides interdisciplinary expertise from the medical and cognitive neuroscience point of view.

Doel van het onderzoek

We hypothesize that tACS can entrain oscillations in individuals with Classic Galactosemia and relevant frequencies such that they result in improvements of their motor and language performance

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

We propose a pre/during/post stimulated mixed design in CG and healthy controls. The intervention consists of tACS at beta and theta frequency in two different sessions to hopefully ameliorate the motor and speech problems in patients with CG. While participants conduct the task, EEG will be measured and compare pre/post tACS.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patient group
The patient may participate in the study, if they meet these criteria:
- Adult age: 18 years or older
- GALT enzyme activity below 10% and/or GALT gene severe disease causing mutations
- Motor sequencing and/or word productions problems
- Documented motor and language impairments
- Capable of giving informed consent
- The participants are screened pre and post intervention using standardized tests. Participants with abnormal scores in cognitive and/or motor domains are eligible.

Control group
Healthy controls are included if they meet the following criteria:
- Adult age: 18 years or older
- No motor, language and/or cognitive impairments
- Capable of giving informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A subject will be excluded from the study, if he meets these criteria:
- Motor and language problems due to other causes
- Eczema
- Psoriasis
- Epilepsy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2020
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8241
Ander register	METC azM/UM : METC 19-055

Resultaten