Transcranial Alternating Current Stimulation (tACS) in Adult Classic Galactosemia

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20217

Source
Nationaal Trial Register

Brief title
NIBS.CG

Health condition

Classic Galactosemia

Sponsors and support

Primary sponsor: azM
Source(s) of monetary or material Support: Galactosemia Foundation

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1) To benchmark individual brain oscillations in CG for the first time and compare them to those of healthy controls.
2) To apply these individualized frequencies with tACS to entrain the relevant brain oscillation
3) To compare EEG and behavior pre and post stimulation to quantify the effect and efficiency of NIBS in CG

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2020
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results