Electrophysiological markers of cortical excitability to predict response to treatment with anti-seizure medication

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To address the potential of cortical excitability measures using TMS-EEG/EMG to differentiate between responders and non-responders to ASM in people with refractory focal epilepsy. The secondary objectives are to validate visual evoked potentials (...

Ethical review	Approved WMO
Status	Completed
Health condition type	Seizures (incl subtypes)
Study type	Observational invasive

Summary

ID

NL-OMON54069

Source
ToetsingOnline

Brief title
The eCORTA Study

Condition

- Seizures (incl subtypes)

Synonym
epilepsy, seizures

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Cenobamate, EEG biomarkers, Epilepsy, TMS

Outcome measures

Primary outcome

Change in cortical excitability parameters using TMS-EEG/EMG concerning

treatment response.

Secondary outcome

- Change in cortical excitability parameters using VEP-EEG, task and resting

state EEG in relation to treatment response

- Utility of excitability parameters at T1 and optional T2 to predict treatment

response on the long term by comparing measures between T0, T1 and optional T2

to seizure reduction after 12 months

- Change in rMT between T0 and T1 correlated to change in seizure

frequency in percentage

- Change in scores calculated from the used questionnaires to determine

anxiety, seizure severity and QOL

Study description

Background summary

Epilepsy is a paroxysmal and unpredictable condition; one-third of people continue to have seizures despite anti-seizure medication (ASM). Treatment appropriateness is decided on a trial and error basis as efficacy can only be determined retrospectively, causing delays in finding the proper treatment. Cortical excitability may provide a biomarker for treatment evaluation. The study aims to measure cortical excitability changes after the initiation of an ASM using transcranial magnetic stimulation (TMS) during EEG and EMG registration (TMS-EEG/EMG), and to validate other EEG biomarkers to measure and

predict treatment response. We hypothesize the cortical excitability will decrease after initiation of cenobamate in responders.

Study objective

To address the potential of cortical excitability measures using TMS-EEG/EMG to differentiate between responders and non-responders to ASM in people with refractory focal epilepsy. The secondary objectives are to validate visual evoked potentials (VEP)-EEG, resting-state EEG and task-EEG in separating responders and non-responders, the potential of the biomarkers as a predictor of treatment success, and evaluate the influence of cenobamate on quality of life (QOL) and anxiety.

Study design

This is a multicentre prospective study. Participants will undergo TMS-EEG/EMG, VEP-EEG, resting-state EEG and task-EEG at baseline (T0), at 100 mg (T1) and optional at a maximum dose (T2). They will keep a seizure diary for twelve months and fill in questionnaires about QOL, anxiety and seizure severity at baseline, at T1, optional T2 and after twelve months.

Study burden and risks

The participants have two or three visits when measurements (TMS-EEG/EMG, VEP-EEG, resting-state EEG and task-EEG) will be performed. Also they will fill in questionnaires about QOL, anxiety and seizure severity at two or three given moments. The largest risk consists of a TMS-induced seizure. This poses a minor risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In agreement with their own neurologist to initiate adjuvant treatment with cenobamate, diagnosed with focal epilepsy, age of 18 years or older, having kept a seizure diary for the past 12 weeks, at least one seizure in the past 12 weeks.

Exclusion criteria

Photosensitive epilepsy, Cochlear implants, implanted neurostimulator or metal in the brain or skull, persistent skull opening following trauma or surgery, cardiac pacemaker, intracardiac lines, evidence (clinical or radiological) of major structural abnormality of the motor cortex or pyramidal tracts, any major psychiatric or neurological (other than epilepsy) condition, pregnancy, learning disabilities.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-03-2022
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	26-01-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-08-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	10-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL77887.058.21

Study results

Date completed: 29-02-2024

Actual enrolment: 9

Summary results
Trial ended prematurely