Evaluation of ANT-DBS Neuromodulation with Sensing Electrodes (EANSkE)

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

Summary

ID

NL-OMON56397

Source
ToetsingOnline

Brief title
EANSkE

Condition

- Seizures (incl subtypes)

Synonym
Epilepsy, medically refractory epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Eigen financiering

Intervention

Keyword: Deep Brain Stimulation (DBS), Epilepsy, Local Field Potentials (LFPs), Neuromodulation

Outcome measures

Primary outcome

The primary goal of the study is to identify biomarkers from LFPs recorded from the DBS electrodes that are associated with treatment response to DBS in patients with epilepsy. Hereby, treatment response is defined by the percentual seizure reduction.

Secondary outcome

- To characterize the short and long latency DBS evoked potentials recorded on the scalp with 64-channels EEG

- To predict success of DBS in patients with epilepsy using pre-operative features from resting-state 64-channel EEG and MRI. We will initially aim to predict responders (>50% seizure reduction at 12 and 24 months after DBS implantation); this binarized response will be complemented by assessing the likelihood of seizure reduction on a continuous scale.

- To improve insight in the role of the thalamocortical network in patients with epilepsy by studying the relation of simultaneous measured LFP recording of the ANT and 64-channel surface EEG recording.

- To study differences in network characteristics derived from 64-channel EEG, and MRI before and after DBS.

- To evaluate the effect of ANT DBS on memory functions (pre- vs post-implantation) tested using standardized neuropsychological examination.

- To evaluate the differences in the power spectral density of ictal (during a seizure) and interictal (when the patient is not having a seizure) LFP measurements.

- To characterize the short and long latency VNS evoked potentials recorded on the scalp with 64-channels EEG, in the subgroup of patient who also have a vagus nerve stimulator (VNS) implanted.

Study description

Background summary

In patients with medically refractory epilepsy who are not eligible for surgical treatment, neuromodulation including deep brain stimulation (DBS) remains as a last resort. However, a good response (> 50% seizure reduction) is achieved in only approximately 70% of patients.
To date, the effects of the stimulation parameters (voltage, frequency, pulse width, and cycling on stimulation) are still poorly understood and no *optimal* set of stimulation parameters is defined. Optimizing stimulation settings for each patient individually is an important aspect of DBS for epilepsy. Currently, this is a very complex task and adjustment of stimulation parameters is based on trial and error and heavily rely on patient seizure diaries. Until now, no biomarkers exist that can guide in this procedure. Recent advances in DBS hardware allow recording of the local field potentials (LFPs) of the neuronal tissue around the electrode. We hypothesize that the combination of this technique with network analysis of resting state fMRI and 64-channel EEG can provide insight in the brain circuits involved in the disturbed brain dynamics and can result in a significant improvement in response evaluation of individual patients with DBS for epilepsy. Analyzing the direct response to DBS stimuli in the EEG (DBS evoked potentials) can also contribute to this.

Study objective

The primary goal of the study is to identify biomarkers from LFPs recorded from the DBS electrodes that are associated with treatment response to DBS in patients with epilepsy. If these biomarkers exist, these can potentially be used to guide treatment therapy as an alternative of seizure diaries in future patients.

Study design

We propose a prospective observational cohort study.

Study burden and risks

The risks of participating in this observational study are very minimal. The study has no influence on the implantation of the DBS system nor on programming the stimulation settings.
Patients will be followed starting from 2 months pre-operative until 24 months postoperative. LFPs will be recorded from the implanted DBS electrodes 1 or 2 days post-operative (during hospital admission) and at 6 additional study visits (1,3,6,12,18 and 24 months postoperative).
Reading-out LFPs from DBS electrodes that already are implanted, can be performed contactless and is without any risk for the patient.
In addition, we will record 64-channel EEG at baseline (before DBS implantation), 1 or 2 days postoperative (during hospital admission), and at 12 and 24 months postoperative. During the EEGs recorded at 12 and 24 months follow-up, the DBS settings will be varied to eanable measuring DBS evoked potentials. MRI scans (anatomical, DTI and fMRI) will be made twice, at baseline and 12 months postoperative. Patients will be asked to keep diaries of their perceived seizures during the study period. We will also ask all patients to fill four questionnaires about psychological well-being at baseline and at 12 and 24 months post-operative.
If we can find biomarkers that can be used in the evaluation of treatment response to DBS therapy these can be used for optimal individual DBS programming in future patients. Therefore, the risk and burden for the participating capacitated adults are in proportion with the potential value of the study,

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

- Adult (>=18 year) patients with medically refractory epilepsy, who are candidates for ANT-DBS or who already have an ANT-DBS implant.
- Implantable pulse generator that allows recording of LFPs (Medtronic Percept system).

Exclusion criteria

Patients with cognitive impairments that causes the patient to be unable to understand the research purpose and give informed consent will be excluded in this study.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2021
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	24-08-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-12-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL74347.100.20
Other	NL9272