Stimulation of the anterior thalamic nucleus in refractory epilepsy: Neurophysiological aspects and effects on cognition

Published: 02-06-2014
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Primary Objective: - To gain insight on the underlying mechanisms of the variability of the response to ATN-DBS in patients with AED refractory epilepsySecondary Objective(s): - To gain insight in the neurophysiology of the anterior thalamic nucleus...

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

Summary

ID

NL-OMON44832

Source
ToetsingOnline

Brief title
Effects of DBS in epilepsy

Condition

- Seizures (incl subtypes)

Synonym
Seizure disorder

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Deep Brain Stimulation, Electrophysiology, Refractory Epilepsy

Outcome measures

Primary outcome

This observational study aims at the registration of ATN signals in the

immediate postoperative stage.

We compare these parameters in groups with good response and patients with poor

response.

Note that these parameters are (up till now) not clinically significant end

points.

Secondary outcome

-

Study description

Background summary

Bilateral stimulation of the anterior thalamic nucleus (ATN-DBS) leads to reduction of seizure frequency in patients who were refractory to medical treatment. The treatment response however varies widely in the trial data, reported by Fisher et al from a 100% response to even an increase in seizure frequency. On average, patients had a decrease of 1/3 of their seizures.

The mechanism of action, but also the cause of the variability in the response remains unclear. These may be related to electrophysiological factors, as during the implantation of the DBS electrode some conspicuous bursts have been found, however, the clinical significance is unclear. It is unknown however whether these specific signals in the anterior thalamic nucleus are more associated with seizures and whether the presence of some specific signal types may predict a higher response rate to ATN-DBS.
On the other hand, it is unclear whether and when patients will experience side

effects of ATN-DBS.
In order to gain insight on the causes of a variable response to ATN-DBS, we plan to register signals from the anterior thalamic nucleus in the acute perioperative stage.

Study objective

Primary Objective:
- To gain insight on the underlying mechanisms of the variability of the response to ATN-DBS in patients with AED refractory epilepsy
Secondary Objective(s):
- To gain insight in the neurophysiology of the anterior thalamic nucleus
- To gain insight on the why and how of the occurrence of side effects in ATN-DBS

Study design

The study design is observational in character. Patients are recruited from the patients who qualify on clinical grounds for treatment with ATN-DBS because of refractory epilepsy. These patients are selected by a multidisciplinary team of specialists (neurologists, neurophysiologists, neurosurgeons, a neuroradiologist, and a neuropsychologist).
Patients receive their treatment (implantation of the DBS electrodes) in the Maastricht University Medical Center.
Procedure:
Peroperative measurements (implantation occurs in general anesthesia):
Registration of neurophysiologic signals from the ATN

Measurements in the direct postoperative stage:
Registration of ATN signals in combination with regular surface electroencephalogram (EEG) during 12 hours, electrical stimulation and cognitive testing

Study burden and risks

Patients probably have no direct benefit from the current study, though there are some minor risks.
The registration period of 12 hours with intracranial electrode has a small risk of infection. In patients with Parkinson*s disease though, this procedure has never led to any complications.
On the other hand, registration of the thalamic signals (which are registered at several different locations along the tip of the electrode) may lead to a better understanding of the thalamocortical signal pathways, and selective stimulation of the point of highest coherence or aberrant signal may lead to higher effectiveness of the ATN-DBS.

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

Medically refractory epilepsy
No possibility for resective epilepsy surgery
Incapacitating epilepsy or seizures (no absolute minimal frequency)
Minimum age 18 years

Exclusion criteria

Underlying malignancies, whenever life expectancy is lower than 2 years
Co-medication with anti-inflammatory drugs or systemic diseases with inflammation are possible exclusion criteria, depending on severity and stability. Whenever there is a stable disease, with a reasonable chance of sustained stability, and stable medication, inclusion is

possible. In other cases, patients will be excluded.
There also may be clinical grounds on which the specialist team may decide that a patient does or does not qualify for ATN-DBS treatment. The team will be more hesitant in case of (co-existent) psychogenic, non-epileptic attacks, or low IQ (below 70).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-07-2015
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	02-06-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	27-12-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL43468.068.13