Ultra-high field MRI in DBS for epilepsy

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By pre-operatively visualizing the thalamus of DBS patients with epilepsy using 7T MRI, we aim to locate clinically effective and ineffective electrode placement relative to the thalamic subnuclei and its connectivity.

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

Summary

ID

NL-OMON48769

Source
ToetsingOnline

Brief title
uhfMRI bij EPI-DBS

Condition

- Seizures (incl subtypes)

Synonym
Epilepsy, Seizures

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: DBS, Epilepsy, Thalamus, Ultra-high field MRI

Outcome measures

Primary outcome

The main radiological endpoint will be the location of the DBS electrode within the thalamic subnuclei and its structural and functional connectivity. De study parameters used are the DBS electrode contact coordinates (in y, x and z directions) and Euclidean distance of the implanted DBS electrode to the thalamic subnuclei defined by segmentation and by structural and functional MRI. The main clinical endpoint will be the reduction in seizure frequency after DBS.

Secondary outcome

not applicable

Study description

Background summary

Deep brain stimulation (DBS) of the thalamus can be an effective therapy for patients with drug-resistant epilepsy who do not qualify for resective epilepsy surgery. However, DBS responder rates vary, possibly due to suboptimal placement of the DBS electrode related to poor visualization of the thalamic subnuclei at low-field strength (1.5T and 3T) MRI. More accurate visualization of the thalamus with ultra-high field (7T) MRI may very likely improve lead placement in the future and thus therapy response. By pre-operatively visualizing the thalamus of DBS patients with epilepsy using 7T MRI, we aim to compare electrode placement and its connectivity between responders and non-responders to DBS.

Study objective

By pre-operatively visualizing the thalamus of DBS patients with epilepsy using 7T MRI, we aim to locate clinically effective and ineffective electrode placement relative to the thalamic subnuclei and its connectivity.

Study design

We will use a prospective observational study design to compare DBS electrode placement in the thalamus and its connectivity in responders and non responders to DBS for epilepsy.

Study burden and risks

There are no additional risks associated with a 7T MRI scan compared to standard 3T MRI scan for participants in this study if contra-indications are taken heed of. A small number of people (~5%) may experience temporary vertigo, nausea, metallic taste or tingling sensations while entering the scanner.

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

All subjects must be mentally competent (wilsbekwaam) and able to understand the patient information form and decide for participation.
All subjects must be aged over 18 years old.
All subjects must meet all inclusion requirements of the standard Scannexus screening form
All subject must be included for DBS surgery at the MUMC+ for treatment of drug-resistant epilepsy

Exclusion criteria

Neurological diseases other than epilepsy, such as brain tumours, stroke, severe neurotrauma*s, and neurodegenerative diseases.
Foreign ferromagnetic objects in the subject*s body or other contra indications for MRI. Prior to scanning, subjects will fill out a screening form. This form will be sent with the information letter to all subjects (Appendices 4 and 5). The screening form will be filled out again on the day of the scan, to ensure any contra indications are known to both the subject and the scanning technician.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-06-2019
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO Date:	01-04-2019
Application type:	First submission
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	NL66101.068.18