Imaging-based evaluation of the treatment of tremor by targeted lesioning of the brain

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21836

Source
NTR

Health condition

Thalamotomy; lesioning; tremor; DTI

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

In all patients: relation between tremor severity and localization of the lesion. Relation between clinical tremor severity and radiographic (DTI) features of the cerebello-rubro-thalamic tract.

- The difference in localization of the lesioned area in the brain towards the preoperative

assessed target measured in millimetres

- The volume of the cerebello-rubro-thalamic tract involved in the lesioned area and compared to the contralateral side

- Tremor severity as measured by accelerometers (amplitude and frequency) and the Bain & Findley Clinical Tremor Rating Scale

Secondary outcome

Patient satisfaction after (sub)thalamotomy using a short questionnaire (VAS score).

Study description

Background summary

Rationale:
In the neurosurgical treatment for medication-refractory debilitating tremor, deep brain stimulation (DBS) is nowadays far more popular than thalamotomy. But in selected cases lesioning may be preferable over DBS. This study aims to learn more about the therapeutic mechanism of (sub)thalamotomy.
A novel MRI technique, Diffusion Tensor Imaging (DTI), can be used to detect microstructural changes in the white matter. It is also applied to visualize white matter tracts in the brain.

Objective:
This evaluation aims to improve the optimal surgical target planning for thalamotomy, and to optimize the selection process of individual patient for either DBS or thalamotomy.

Study design:
Participants will have a clinical evaluation consisting of:

- Tremor registration and video registration, followed by a clinical tremor rating scale assessment

- Short questionnaire about patient satisfaction

- Repeat MRI with diffusion weighted imaging

Study population:
A cohort of 19 patients who were treated with (sub)thalamotomy in the UMC Groningen is

eligible.

Main study endpoints:
- Difference in localization of lesioned area towards preoperative assessed target (in millimeters)

- Volume of the cerebello-rubro-thalamic tract involved in the lesioned area and compared to the contralateral side

- Tremor severity as measured by accelerometers (amplitude and frequency) and the Bain & Findley Clinical Tremor Rating Scale

- Patient satisfaction after (sub)thalamotomy using a short questionnaire (VAS score)

Study objective

This study aims to improve the optimal surgical target planning for thalamotomy, and to optimize the selection process of individual patients for either DBS or (sub)thalamotomy.

Study design

MRI and tremor registration will be scheduled on the same day if possible.

Intervention

- Tremor registration and video registration, followed by a clinical tremor rating scale assessment

- Short questionnaire about patient satisfaction

- Repeat MRI with diffusion weighted imaging

Contacts

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Eligibility criteria

Inclusion criteria

- Adult patients (>18 years old)

- Treatment for tremor with (sub)thalamotomy in the UMCG

- Written informed consent

Exclusion criteria

- Contra-indications to MRI examination (e.g. heart pacemaker, metal foreign body in eye, aneurysm clip in brain, severe claustrophobia)

- Implantation of DBS electrodes

- Patients with a life expectancy less than 6 months

- Patients physically not able to lie flat for one hour

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2016
Enrollment:	19
Type:	Anticipated

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	NL4462
NTR-old	NTR5704
Other	METc : 2015/597

Study results