Evaluation of the cerebello-rubrothalamic tract after (sub)thalamotomy.

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Primary Objective: • To investigate the difference in localization of the lesioned area in the brain towards the preoperative assessed target and relate this to registration and rating of clinical tremor.• To investigate the role of the dentato-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON43426

Source ToetsingOnline

Brief title Evaluation (sub)thalamotomy.

Condition

• Movement disorders (incl parkinsonism)

Synonym shaking, tremor

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: DTI, MRI, thalamotomy, tremor

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 dentato-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

Stereotactic functional neurosurgery is a valid option in the treatment of medication-refractory debilitating tremor, caused by various conditions such as Parkinson*s Disease (PD), Multiple Sclerosis (MS), and Essential Tremor (ET). The goal of the surgery is to suppress the tremor with either a very precise lesion, so-called (sub)thalamotomy, or with a stimulating electrode in a particular area of the brain, so-called deep brain stimulation (DBS). The

latter option is nowadays far more popular than lesioning. Important arguments to prefer DBS are its bilateral application, its adjustability and its reversible side-effects. On the other hand, DBS is a lifelong therapy with high costs and other disadvantages. Therefore, in selected cases lesioning may be preferable over DBS. This project aims to learn more about the therapeutic mechanism of (sub)thalamotomy.

Various parts of the brain can be lesioned to treat tremor. For this project the thalamic Ventral InterMediate nucleus (VIM) and the subthalamic Zona Incerta (ZI) are the targets of interest for this study. Multiple patients received unilateral stereotactic lesion surgery of one of these nuclei over the past 25 years in the UMC Groningen. In order to accomplish a successful neurosurgical intervention it is critical to establish the exact coordinates of the target. In most cases the nucleus is calculated based on an anatomical atlas in relation to the anterior commissure - posterior commissure (AC-PC) line, but it is obvious that this indirect method does not take individual anatomical variations in account. Recent developments in radiological imaging have opened the possibility to point out the VIM or ZI directly on high field strength MRI of the brain. It seems obvious that this new direct method of targeting can effectuate better clinical results than (sub)thalamotomy did in the past.

A novel MRI-technique, Diffusion Tensor Imaging (DTI), is based on the diffusion of water molecules in the brain and can be used to detect microstructural changes in the white matter. It is also applied to visualize white matter tracts in the brain. DTI is a cutting edge technique, which makes it difficult to choose the correct algorithms and settings. Therefore, ongoing research is performed to evaluate the relevancy and accuracy of DTI.

This evaluation 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 objective

Primary Objective:

• To investigate the difference in localization of the lesioned area in the brain towards the preoperative assessed target and relate this to registration and rating of clinical tremor.

• To investigate the role of the dentato-rubro-thalamic tract in lesioning the VIM or ZI and relate this to registration and rating of clinical tremor.

Secondary Objectives:

• To investigate the patient satisfaction after (sub)thalamotomy.

Study design

The design of the project will be partially retrospective (chart and imaging review) and partially prospective (repeated tremor registration, tremor score, MRI-DTI and assessment of patient satisfaction).

A cohort of 19 patients that underwent (sub)thalamotomy in the UMC Groningen will be asked to participate. We expect almost every patient to participate. 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 (DTI)

All patients had preoperative tremor registration. We want to evaluate whether the severity of tremor has changed postoperatively. Therefore, patients receive a postoperative tremor registration and video registration. Video registration is a common instrument in the department of movement disorders. With use of video images, tremor severity can be assessed using the Bain & Findley Clinical Tremor Rating Scale [11]. Since (sub)thalamotomy is done unilaterally, tremor severity on the lesioned side is related to the contralateral side. Additionally, patients are asked to fill out a short questionnaire about patient satisfaction. Subjective tremor severity will be related to objective tremor severity.

The repeat MRI-DTI is evaluated in the context of the previous imaging. All patients had preoperative MRI and postoperative MRI and/or CT examinations. The preoperative MRI was used to determine the target during the surgery. Postoperative images were obtained to exclude surgical complications (e.g. hemorrhage). The surgical planning data are saved in the patients charts. Coordinates of the planned surgical targets are to be related to the position where targets are actually localized on the follow-up MRI. This is done by digital merging of the pre- and postoperative MRI. There is extensive experience in using this software (BrainLab) in the department of neurosurgery. The DTI data of the cerebello-rubro-thalamic tract on the lesioned side is related to the surgical target, as well as compared with the tract on the contralateral side.

Study burden and risks

Patients will be included from February 2016 untill April 2016. Invitations will be done telephonically, followed by mailing of study documents. Patients provide written informed consent on the day of visit. Patients will get tremor registration and video registration, a short questionnaire about patient satisfaction on the same day. MRI will be scheduled on the same day if possible.

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 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,

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2016
Enrollment:	19
Туре:	Actual

Ethics review

Approved WMO	
Date:	02-02-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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

ССМО

ID NL55655.042.15