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

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21836

Bron
NTR

Aandoening

Thalamotomy; lesioning; tremor; DTI

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

- Short questionnaire about patient satisfaction

- Repeat MRI with diffusion weighted imaging

Contactpersonen

Publiek

UMCG
D.L.M. Oterdoom
Groningen
The Netherlands

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Adult patients (>18 years old)

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

- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2016
Aantal proefpersonen:	19
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4462
NTR-old	NTR5704
Ander register	METc : 2015/597

Resultaten