Operative Motor-tract Excitation during General Anesthesia for Deep Brain Stimulation

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There is a correlation between the threshold to elicit a MEP by stimulating the DBS lead and the distance between the DBS lead and the internal capsule

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON20579

Bron
NTR

Verkorte titel
OMEGA-DBS

Aandoening

Dystonia

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

o MEP thresholds, obtained during the surgery

o Distances in mm from DBS lead to IC, measured on intraoperative CT

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
A well-known and serious side-effect of deep brain stimulation (DBS) is activation of the motor-tract (corticospinal tract), anatomically located in the internal capsule. To ensure a safe distance between the DBS lead and the motor-tract, intraoperative testing in an awake setting is utilized. Since awake surgery is often impossible for dystonic patients, an objective measure to ensure safe distance to the motor-tract during general anesthesia is lacking.

Objective:
To determine the correlation between the threshold of the motor evoked potential (MEP) stimulated via the DBS-lead and the (safe) distance between the DBS-lead and the internal capsule (IC).

Study design:
An intraoperative stimulation protocol is applied to determine the MEP-threshold of contralateral muscles by stimulation via the DBS-lead in dystonic patients under general anesthesia. Since the IC and DBS-lead both are depicted on postoperative imaging, the MEP-threshold is compared with the shortest distance between these structures.

Study population:
Adult dystonic patients undergoing DBS of the Globus Pallidus internus (GPi).

Main study parameters/endpoints:
The primary endpoints of the study are the threshold of the MEP during surgery and the distance between the DBS lead and the IC on intraoperative imaging.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The NIM-Eclipse intraoperative neuromonitoring system (Medtronic) will be attached to the DBS-leads, which is considered off-label use of this system. Subjects are not submitted to additional risks.
If there is a the correlation between the MEP-threshold and the distance from the DBS lead to the IC, the NIM-Eclipse system can serve as an intraoperative tool to ensure safe distance between these two structures.

Doel van het onderzoek

There is a correlation between the threshold to elicit a MEP by stimulating the DBS lead and the distance between the DBS lead and the internal capsule

Onderzoeksopzet

During surgery

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Dystonia patients undergoing bilateral GPi-DBS surgery under general anaesthesia in the University Medical Center Groningen

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

Onderzoeksopzet

Opzet

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	14-06-2021
Aantal proefpersonen:	5
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL9557
Ander register	METC UMCG : METCXXX

Resultaten