

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	-

## Summary

### ID

NL-OMON20579

### Source

NTR

### Brief title

OMEGA-DBS

### Health condition

Dystonia

## Sponsors and support

**Primary sponsor:** UMCG

**Source(s) of monetary or material Support:** UMCG

## Intervention

## Outcome measures

### Primary outcome

- o MEP thresholds, obtained during the surgery
- o Distances in mm from DBS lead to IC, measured on intraoperative CT

## Secondary outcome

None

## Study description

### Background summary

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 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.

### Study objective

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

## Study design

During surgery

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

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

### Exclusion criteria

None

## Study design

### Design

Intervention model: Other

Allocation: Non controlled trial

**Control:** N/A , unknown

## Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 14-06-2021

Enrollment: 5

Type: Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## 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	NL9557
Other	METC UMCG : METCXXX

## Study results