A multi-center observational study on the Prevalence of Loss of benefit after DBS for medication-refractory tremor

Published: 06-12-2022
Last updated: 30-11-2024

The primary objective of this research is to determine the prevalence and magnitude of loss of benefit from DBS stimulation in patients who underwent DBS surgery for upper extremity tremor that was refractory to medical management. The secondary…

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

Summary

ID

NL-OMON51271

Source
ToetsingOnline

Brief title
Loss of benefit after DBS in tremor patients

Condition

- Movement disorders (incl parkinsonism)

Synonym
shaking, tremor

Research involving
Human

Sponsors and support

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

Intervention

Keyword: dbs, essential tremor, tolerance, tremor

Outcome measures

Primary outcome

Primary outcome variables: Loss of benefit and categorical loss of benefit.

Secondary outcome

Secondary outcome variables: Rebound tremor and overshoot benefit.

Study description

Background summary

Loss of DBS benefit is arguably an important research topic in DBS for medication-refractory tremor. We are seeking a better understanding of the clinical factors that predict loss of DBS benefit, and we seek a better understanding of the contribution of tolerance to loss of DBS benefit.

Study objective

The primary objective of this research is to determine the prevalence and magnitude of loss of benefit from DBS stimulation in patients who underwent DBS surgery for upper extremity tremor that was refractory to medical management. The secondary object is to determine the relationship between loss of benefit and rebound tremor and overshoot benefit.

Study design

This is an investigator-initiated, observational, single-visit, multi-center study.

Study burden and risks

Due to the very specific aim of this study, only patients suffering from tremor treated with DBS can participate. The study protocol is safe, non-invasive and part of standard clinical routines. Switching DBS off might be bothersome for patients as symptoms will temporarily increase during this time period, which will be limited to the duration of the study visit.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients of any age over 18 who are capable of understanding and granting informed consent.
2. Patients who have undergone unilateral or bilateral DBS surgery for medication-refractory upper extremity tremor at least 5 years prior to recruitment. The upper limit for the time since surgery will be 15 years. Long intervals are specifically welcome.
3. Preoperative diagnosis of ET, ET plus or isolated dystonic tremor as defined by the tremor task force of the international Parkinson and Movement Disorders Society consensus in 2018 (Bhatia et al., 2018).
4. Availability of retrospective clinical baseline and early postoperative data, including tremor scales (see below 4.3.4).
5. Stable tremor medications and stimulation settings for at least 2 months

prior to the study visit.
6. Patients must be able to follow the assessment procedure.

Exclusion criteria

1. Concomitant diseases that may confound the neurological findings.
2. DBS hardware malfunction (e.g., battery or electrode failure).
3. Significant cognitive impairment that may make patient unable to follow assessment procedure.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-11-2023
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	06-12-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL82457.018.22