Longitudinal recordings of local field potentials in movement disorder patients implanted with deep brain stimulation electrodes

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Compare neurophysiological biomarkers with symptom control and stimulation parameters to improve stimulation settings for individual patients with Parkinson*s disease, tremor syndromes and dystonia.

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

Summary

ID

NL-OMON54252

Source
ToetsingOnline

Brief title
Longitudinal recordings in patients implanted with DBS electrodes

Condition

- Movement disorders (incl parkinsonism)

Synonym
movement disorders, shaking

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, dystonia, parkinson, tremor

Outcome measures

Primary outcome

Primary end points per study part:

Part A: correlation of disease specific neural oscillations ON and OFF

stimulation (full-spectrum (0-125 Hz) recordings) with symptom severity.

Part B: relation between neural oscillations with DBS switched ON and OFF,

their interaction with symptom severity, and their stability during multiple

measurements over time.

Part C: relation between PD motor and non-motor symptoms, motivational state,

smartwatch kinematics and neural oscillations over a 2-week at-home

intervalrelation between the presence of disease

Secondary outcome

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Study description

Background summary

Deep brain stimulation (DBS) has been one of the most important therapeutic development for patients with advanced Parkinson*s disease, tremor syndromes and dystonia in the past 30 years. Novel developments in DBS devices provide the opportunity to longitudinally record neurophysiological signals from implanted brain regions. This is crucial to better understand the therapeutic effect of DBS, and for the development of so called adaptive deep brain stimulation (aDBS). This novel method concurrently measures biomarkers related to severity of symptoms, and adjusts stimulation based on these signals.

Comparing these longitudinally recorded signals with symptom control and stimulation parameters will help to improve the clinical efficacy of DBS for patients, and aid in individualised therapy.

Study objective

Compare neurophysiological biomarkers with symptom control and stimulation parameters to improve stimulation settings for individual patients with Parkinson*s disease, tremor syndromes and dystonia.

Study design

This is a longitudinal prospective cohort study that will include patients with three types of movement disorders: Parkinson*s disease, tremor and dystonia who are implanted with a new DBS device (Medtronic Percept* PC neurostimulator) as part of standard clinical care. This study will consist of three parts, patients can opt out for part B/C or part C on an individual basis.
Part A (study visit 1): 15-minute recordings with stimulation switched OFF and ON. Patients will be invited for participation in this study at least 1 week after surgery.
Part B (study visit 2 and 3): 15-minute recordings with stimulation switch OFF and ON. Read out of recordings of the previous 4 weeks saved on the neurostimulator during two standard visits at the outpatient clinic, or through two additional visits to the outpatient clinic if no standard visit is scheduled or necessary.
Part C (surveys, decision-making paradigm, LFP recording, smartwatch - at home for 2 weekssmartwatch and patient journal at home for 4 weeks in between visit 2 and 3): Between visit 1 and 2, or 2 and 3, patients will fill in a digital diary for a 4-week period prior to their visit. They will do this on the DBS patient programmer device. They will also wear a smartwatch for a 4-week period to measure symptom severity. twice a day (once with stimulation on, and once with stimulation off) patients will administer surveys indexing PD motor and non-motor symptoms, perform a decision-making paradigm assessing motivational state, and trigger a broadband local field potential (LFP) recording via their DBS programmer. Kinematics and narrowband LFP recording will be collected passively and continuously via a smartwatch and the DBS device respectively.

Study burden and risks

Due to the very specific aim of this study, only patients suffering from advanced Parkinson*s disease, tremor or dystonia can participate. Readout of recordings is safe and non-invasive. Switching DBS off might be bothersome for patients as symptoms will temporarily increase during this time period, which will be limited to 30 minutes. Extra visits to the outpatient clinic might be involved.

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

- Newly implanted patient with the Medtronic Percept* PC neurostimulator, and diagnosed with Parkinson*s disease, tremor or dystonia (nb this can be during the first DBS lead implantation or during the repacement of the prior DBS neurostimulator).
- Informed consent
- Age 18 years or older

Exclusion criteria

- Patients implanted with the Medtronic Percept* PC neurostimulator with other other indications than Parkinson's disease, tremor or dystonia

- Patients implanted with a Medtronic DBS Pocket Adaptor Model 64001 or 64002. These DBS systems are not compatible with BrainSenseTM technology.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-09-2020
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Percept PC neurostimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-09-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-09-2023

Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	11-12-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL74645.018.20