AI-DBS: Applying Personalized Deep Brain Stimulation using *Neuronal Fingerprints*

Published: 15-08-2022
Last updated: 20-06-2024

Improving the clinical effect and efficiency of DBS for PD by investigating patient specific patterns of neuronal cell activity in the brain that are associated with symptom-severity. This may improve the clinical effect of DBS, and also result in...

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

Summary

ID

NL-OMON51791

Source
ToetsingOnline

Brief title
AI-DBS

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson Disease, shaking

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Medtronic,Ministerie van Economische Zaken en Klimaat;Medtronic en Rune Labs,Rune Labs

Intervention

Keyword: Artificial Intelligence, Deep Brain Stimulation, Neuronal Fingerprints, Parkinson's Disease

Outcome measures

Primary outcome

The development of a patient specific profile of neuronal activity that is

associated with the presence and severity of the symptoms, forming a *neuronal

fingerprint*.

Secondary outcome

N\A

Study description

Background summary

Deep brain stimulation (DBS) is a very efficacious treatment for Parkinson*s disease (PD). However, the programming of DBS is a laborious process and requires frequent hospital visits. Furthermore, current DBS protocols use continuous electric current at constant intensity, which may hamper efficacy and induce side-effects.

Study objective

Improving the clinical effect and efficiency of DBS for PD by investigating patient specific patterns of neuronal cell activity in the brain that are associated with symptom-severity. This may improve the clinical effect of DBS, and also result in less burdensome hospital visits, thereby reducing healthcare consumption.

Study design

A longitudinal prospective diagnostic study that will include patients with PD who are implanted with a DBS-sensing system (PerceptTM PC, Medtronic). In the first six months after implantation, neuronal activity will be recorded. The data will be correlated with symptom-severity, assessed with (i) kinematic smartwatch data, (ii) clinical rating scales and (iii) patient diaries, and

analyzed using artificial intelligence (AI) algorithms.

Study burden and risks

Patients will not directly benefit from their participation. However, stimulation parameters might be changed after the experiment if collected data indicates possible advantages. Disadvantage of participation is limited since readout of the neural recordings is safe and non-invasive. The project does not bear any risks and adds only slight discomfort of wearing a smartwatch, making small diary notes and undergoing two extra testing moments, partly without Parkinson's medication (off-drugs). In the AMC, participation includes five test moments, two of which may be extra compared to care as usual. Patients are off-drugs during visits 2 and 5, which is already the case during the normal procedure. At the HagaZiekenhuis, the study includes six outpatient visits and one clinical visit one day postoperatively. Of these, two visits are extra compared to care as usual. Patients are off-drugs during all visits except visit 4. This can cause additional symptoms of Parkinson's disease, but at that time patients already have an active DBS system, which suppresses the symptoms (possibly to a lesser extent than with medication).

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

- Age 18 years or older
- Diagnosed with Parkinson's Disease and eligible for DSB
- Parkinson's Disease patients receiving Medtronic PerceptTM PC STN DBS in the care as usual setting between

Exclusion criteria

- Inability to provide informed consent

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):	26-09-2022
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	PerceptTM PC Neurostimulator

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-08-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-03-2024
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:	11-06-2024
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	NL80384.018.22