Smart brain stimulation in Parkinson’s disease

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23016

Source
NTR

Health condition

Parkinson’s Disease

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Hersenstichting

Intervention

Outcome measures

Primary outcome

blinded Unified Parkinson’s Disease Rating Scale part III score

Secondary outcome

I blinded Speech Intelligibility Test score

II blinded Unified Dyskinesia Rating Scale

III amount of stimulation

Study description

Background summary

Rationale: Deep brain stimulations (DBS) is an established treatment for movement disorders like Parkinson’s Disease (PD), dystonia and Essential Tremor (ET). With DBS, small electrical pulses are applied to deep brain nuclei which lead to motor improvements in these disorders. Although DBS has been successfully applied for over 25 years there are still limitations in terms of effectiveness, side-effects and energy consumption. There is evidence that all these limitations might all be due to excessive electrical stimulation. The mechanism of the limited effectiveness and side-effects could be due to the fact that both pathological and physiological neural activity are disturbed with conventional, continuous DBS (cDBS). Very recent studies have found evidence that DBS might work better were it only to stimulate when necessary. This type of stimulation is called adaptive DBS (aDBS) and uses neurophysiological signals as indicator of symptom severity and trigger to stimulate.
Objective: Test whether aDBS is non-inferior to cDBS in terms of effectiveness and superior in terms of side-effects and energy consumption in patients with Parkinson’s disease.

Study objective

Adaptive Deep Brain Stimulation (DBS) based on neurophysiological biomarkers is equally effective as continuous DBS with less side-effects and energy consumption.

Study design

Primary: after 15 minutes of stimulation

Secondary I: after 20 minutes of stimulation

Secondary II: after 15 minutes of stimulation

Secondary III: 15 minute interval

Intervention

Intervention:
- application of adaptive deep
brain stimulation

Control interventions:
- continous stimulation

- no stimulation

Contacts

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Eligibility criteria

Inclusion criteria

sound of mind

eligible for battery replacement surgery

ability to provide written informed consent

ability to undergo testing in the OFF medication state

physical condition that enables 90 minutes of testing

Exclusion criteria

all contra-indications that apply to normal DBS surgery (eg pregnancy, life expectancy of less than one year)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2016
Enrollment:	16
Type:	Anticipated

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	NL5232
NTR-old	NTR5456

Register	ID
Other	NL54475.042.15 : ABR

Study results

Summary results

Little S, Beudel M, Zrinzo L, et al. Bilateral adaptive Deep Brain Stimulation is effective in Parkinson’s disease. J Neurol Neurosurg Psychiatr. 2015 (In Press)