Adaptive neuromodulation for movement disorders.

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Test whether aDBS is superior to continuous DBS (cDBS) in terms of effectiveness, side-effects and energy consumption in patients with Parkinson*s disease (PD) and dystonia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON42422

Source
ToetsingOnline

Brief title
adaptive DBS

Condition

- Movement disorders (incl parkinsonism)

Synonym
dystonia, Parkinson's disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: closed loop, deep brain stimulation, movement disorders, neurophysiology

Outcome measures

Primary outcome

PD

clinical effect of aDBS compared placebo and cDBS based on blinded clinical

ratings

dystonia:

feasibility and tolerability of aDBS based on LFP low-frequency power

Secondary outcome

PD

side effect profile of aDBS compared to cDBS and placebo

energy consumption of aDBS compared to cDBS

dystonia:

effect of aDBS on subcortico-muscular coherence and clinical ratings

energy consumption of aDBS compared to cDBS

Study description

Background summary

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.

Study objective

Test whether aDBS is superior to continuous DBS (cDBS) in terms of effectiveness, side-effects and energy consumption in patients with Parkinson*s disease (PD) and dystonia.

Study design

PD: Double-blind head-to head placebo controlled intervention study. Dystonia: pilot study.

Intervention

Application of adaptive DBS (aDBS) in patients who have already implanted DBS electrodes.

Study burden and risks

PD
During the DBS battery replacement surgery patient will stay in theatre for 90 minutes longer than usual. During this 90 minutes patients will mainly undergo clinical testing during a new form of stimulation which is proven safe. Given the sterile environment in theatre, there is virtually no increased risk of infections and there are no extra surgical procedures required. Patients will be tested OFF medication. This will exaggerate symptoms to certain extend.

Dystonia
In dystonia, aDBS will be applied after the placement of the DBS electrodes but before the battery placement. In dystonia the experimental procedure will last approximately 15 minutes and the burden and risks is similar to that of the PD patients.

All patients
There is no direct benefit from participation in the study. However, given the current DBS hardware developments it is very likely that new adaptive strategies can be applied within the next five years.

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

PD
- 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
Dystonia:
- sound of mind
- eligible for DBS surgery
- ability to provide written informed consent
- dystonia in at least one muscle that is suitable for prolonged EMG recording

Exclusion criteria

all contra-indications that apply to normal DBS surgery (eg pregnancy, life expectancy of less than one year)
< 18 yo
other disorder that interferes with clinical assessment

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2016
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	21-09-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-05-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-10-2017

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL54475.042.15
Other	NTR nummer volgt