Smart brain stimulation in Parkinson’s disease

Gepubliceerd: 09-09-2015 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23016

Bron
NTR

Aandoening

Parkinson’s Disease

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Hersenstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

blinded Unified Parkinson’s Disease Rating Scale part III score

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Intervention:
- application of adaptive deep
brain stimulation

Control interventions:
- continous stimulation

- no stimulation

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2016
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5232
NTR-old	NTR5456
Ander register	NL54475.042.15 : ABR

Resultaten

Samenvatting resultaten
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)