Intra-operative evaluation of efficacy and safety of a new lead for steering Deep Brain Stimulation.

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Primary Hypothesis: 1. Sapiens lead is able to provide stimulation to the brain safely and elicit equivalent effects as commercial DBS systems. Secondary Hypotheses: 1. Steering can modulate the thresholds of stimulation-induced effects; 2....

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20700

Bron
NTR

Verkorte titel
FAME

Aandoening

Parkinson's disease, Deep Brain Stimulation
Ziekte van Parkinson, Diepe Hersenstimulatie

Ondersteuning

Primaire sponsor: Sapiens Steering Brain Stimulation B.V.
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Overige ondersteuning: Sapiens Steering Brain Stimulation B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Description of and threshold for effects obtained by stimulation through Sapiens lead in standard mode;
2. Analysis of safety of stimulation with the Sapiens lead compared to control data.

Toelichting onderzoek

Achtergrond van het onderzoek

Deep brain stimulation (DBS) currently performed using leads with 4 large electrodes may cause side effects, along with the clinical effect. This could be caused by the unwanted stimulation of adjacent structures. The new Sapiens lead employs a larger number of smaller electrodes. Using this lead, stimulation can be steered selectively towards targeted areas, thus avoiding stimulation of other structures.

Primary objective of the study is to confirm that stimulation through the Sapiens lead is acutely safe and able to produce equivalent effects as stimulation through currently available commercial DBS leads.

Secondary objectives are to establish that “steering” stimulation with a Sapiens lead affects the threshold for stimulation-induced effects, and to demonstrate the ability of the Sapiens lead to optimize the therapeutic window.

The study is a Dutch, single-centre, single-group performance and safety study, conducted acutely during regular DBS surgery with an observational period of two months following surgery, on individuals suffering from Parkinson’s disease who are undergoing deep brain stimulation surgery.

The knowledge coming from this study will be used for the optimization and realization of a new stimulation device, capable of steering stimulation, which could help to decrease the

incidence and severity of side effects associated with chronic deep brain stimulation. This may result in a more effective and long-lasting stimulation therapy for future generation of patients undergoing DBS therapy.

Doel van het onderzoek

Primary Hypothesis:

1. Sapiens lead is able to provide stimulation to the brain safely and elicit equivalent effects as commercial DBS systems.

Secondary Hypotheses:

1. Steering can modulate the thresholds of stimulation-induced effects;

2. The tuning of the stimulation configuration of the Sapiens lead provides the option to optimize the therapeutic window.

Onderzoeksopzet

Acute test.

Onderzoeksproduct en/of interventie

Sapiens Deep brain stimulation lead.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosis of idiopathic Parkinson's disease;

2. Clinical indication for STN DBS with MER;

3. Age > 18 years;

4. Subject is a male or non-pregnant female;

5. Ability to comply with the study assignments;

6. Ability to give informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Parkinson's disease graded according to Hoehn and Yahr stage 5;

2. Score on MATTIS dementia rating scale <120;

3. Psychiatric contraindications to STN DBS;

4. General contraindications for stereotactic surgery and general anaesthesia (e.g. severe hypertension, blood coagulation disorder);

5. Subject has factors that would put the subject at an additional risk for intra-operative or postoperative bleeding. This includes underlying disorders of the coagulation cascade (eg, hemophilia), disorders that affect platelet count or function (eg, Von Willebrand's disease), as well as administration of any anti-platelet or anti-coagulant medication in the 7 days prior to surgery, or any history of anticoagulant or aspirin use or history of hemorrhagic stroke, that in the view of the neurosurgeon or neurologist would place the subject at an increased risk

for intra-operative or postoperative bleeding;

6. Subject has a diagnosis of acute myocardial infarction or cardiac arrest less than or equal to 6 months prior to the screening testing;

7. Subject has a history of a seizure disorder;

8. Subject requires short surgery time due to general health issues, as determined by the investigator;

9. Subject is a woman who is pregnant or planning to become pregnant, or a woman of child-bearing potential, who is not using a medically-acceptable method of birth control. Women of child-bearing potential must undergo a pregnancy test, with a clear negative result, no more than 7 days prior to the investigational procedure visit.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-10-2012
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-10-2012
Soort:	Eerste indiening

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	NL3475
NTR-old	NTR3655
Ander register	CCMO : S-12-0076 / NL40206.018.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A