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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

# **Summary**

## ID

NL-OMON20700

Source NTR

**Brief title** FAME

#### **Health condition**

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

## **Sponsors and support**

Primary sponsor: Sapiens Steering Brain Stimulation B.V. H.C.F. Martens, PhD Director of Clinical Science High Tech Campus 48 5656 AE Eindhoven The Netherlands Tel: +31 40 800 2104 Source(s) of monetary or material Support: Sapiens Steering Brain Stimulation B.V.

## Intervention

## **Outcome measures**

#### **Primary outcome**

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.

#### Secondary outcome

1. Description of and threshold for effects obtained by stimulation through Sapiens lead in different modes;

2. Determination and comparison of "therapeutic window"], obtained by stimulation through Sapiens lead in different modes.

# **Study description**

#### **Background summary**

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

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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.

#### **Study objective**

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.

#### Study design

Acute test.

#### Intervention

Sapiens Deep brain stimulation lead.

# Contacts

#### Public

Academic Medical Center (AMC), department of Neurosurgery, P.O. Box 22660 P.R. Schuurman Meibergdreef 9 Amsterdam 1100 DD The Netherlands +31 (0)20 5669111

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#### Scientific

Academic Medical Center (AMC), department of Neurosurgery, P.O. Box 22660 P.R. Schuurman Meibergdreef 9 Amsterdam 1100 DD The Netherlands +31 (0)20 5669111

# **Eligibility criteria**

# **Inclusion criteria**

- 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.

# **Exclusion criteria**

- 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 childbearing 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.

# Study design

## Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	22-10-2012
Enrollment:	10
Туре:	Anticipated

# **Ethics review**

Positive opinion	
Date:	08-10-2012
Application type:	First submission

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

# **Study results**

Summary results N/A