Intra-operative evaluation of efficacy and safety of a new lead for steering Deep Brain Stimulation. First Acute-in-Man Evaluation of Steering Brain Stimulation (FAME)

Published: 09-08-2012
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The aim of the study is to show safety and effectiveness of the Sapiens electrode in an acute, intra-operative setting.

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

Summary

ID

NL-OMON39039

Source
ToetsingOnline

Brief title
FAME

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease, stifness, tremors

Research involving
Human

Sponsors and support

Primary sponsor: Sapiens Steering Brain Stimulation BV
Source(s) of monetary or material Support: Sapiens Steering Brain Stimulation BV

Intervention

Keyword: deep brain stimulation, intra-operative study

Outcome measures

Primary outcome

1) To confirm that stimulation through the Sapiens lead is safe and able to

produce equivalent effects as stimulation through currently available

commercial DBS leads.

Secondary outcome

2) To establish that steering stimulation with the Sapiens lead modulates the

threshold for stimulation-induced effects as found in *ring mode* through the

same Sapiens lead

Study description

Background summary

Stimulation performed through the currently used large annular electrodes may induce side-effects by stimulating adjacent structures, along with the target nucleus. By selectively activating part of the 32 electrodes on the Sapiens lead, stimulation can be precisely steered towards the targeted areas, sparing other structures.
Selective stimulation can minimize the simultaneous involvement of adjacent structures. This is expected to increase the threshold for stimulation-induced side-effects, while leaving the threshold for therapeutic benefit unchanged. This improvement of the so-called "therapeutic window" will make it easier to obtain and maintain an effective clinical benefit. Moreover, the Sapiens lead will be also able to reproduce the same field of stimulation - and stimulation effects - of the currently available electrode, so that it could be used in

exactly the same way if needed.

Study objective

The aim of the study is to show safety and effectiveness of the Sapiens electrode in an acute, intra-operative setting.

Study design

The study is a single-center, single-group, performance and safety study, conducted acutely during regular DBS surgery with an observational period of two months following surgery.

Intervention

NA

Study burden and risks

The FAME study may give direct benefit to the individual study participants and to the group of (future) patients eligible for DBS as a whole:

Individual benefit
Test stimulation with an acute electrode is part of the common DBS procedure to determine the optimal location for the chronic lead placement. Stimulation with the Sapiens lead is anticipated to confirm the selected location for the chronic DBS lead. However, in situations where use of the Sapiens lead indicates that the chronic DBS position could be optimized further in relation to what is achieved with the routine surgical targeting technique - at the discretion of the surgical team - this additional information could be taken into account to refine placement of the chronic commercial DBS lead.

Group benefit
The knowledge coming from this study will be used for the optimization and realization of a new stimulation device (Sapiens lead and stimulating system). This new device has an innovative lead which carries many potential advantages with respect to the currently available devices. In particular, the possibility of efficaciously steering stimulation would help decrease the incidence and severity of side effects associated with chronic deep brain stimulation, thus improving the therapeutic window. A better therapeutic window may result in a more effective and long-lasting stimulation therapy for future generation of patients undergoing DBS therapy.

Conclusion
Individual benefits to patients participating in the study are limited since the novel Sapiens lead will be used only in the acute setting. The potential

individual patient benefits amounts to a confirmation of the target determined by routine procedure or an improved targeting for the chronic commercial DBS system.
Potential benefits for future patients eligible to DBS are the improved therapeutic window of the DBS therapy owing to the novel Sapiens lead design. The versatility in tuning the stimulation settings with the new Sapiens lead may reduce the incidence of stimulation-induced side-effects and may increase the therapeutic window available for chronic DBS.
Therefore, it is concluded that the benefits of the FAME study outweigh the risks associated with the study.

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

• Diagnosis of idiopathic Parkinson*s disease
• Clinical indication for STN DBS with MER.
• Age > 18 years
• Subject is a male or non-pregnant female
• Ability to comply with the study assignments.
• Ability to give informed consent.

Exclusion criteria

• Parkinson*s disease graded according to Hoehn and Yahr stage 5
• Score on MATTIS dementia rating scale <120
• Psychiatric contraindications to STN DBS
• General contraindications for stereotactic surgery and general anaesthesia (e.g. severe hypertension, blood coagulation disorder)
• 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.
• Subject has a diagnosis of acute myocardial infarction or cardiac arrest less than or equal to 6 months prior to the screening testing.
• Subject has a history of a seizure disorder.
• Subject requires short surgery time due to general health issues, as determined by the investigator.
• 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.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2012
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Deep brain stimulation lead
Registration:	No

Ethics review

Approved WMO

Date:	09-08-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	05-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL40206.018.12