Deep brain stimulation for Parkinson's Disease: a feasibility study on anatomical, functional and diffusionweighted MRI

Published: 11-07-2008 Last updated: 06-05-2024

The goal of the entire PhD project is to find the motor part of the STN using advanced image acquisition and image analysis. To reach this eventual goal, we first have to be able to visualize the STN as a whole. Published studies show only 2D-images...

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

Summary

ID

NL-OMON32349

Source ToetsingOnline

Brief title MRI for deep brain stimulation

Condition

• Movement disorders (incl parkinsonism)

Synonym Parkinson's Disease

Research involving Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht

1 - Deep brain stimulation for Parkinson's Disease: a feasibility study on anatomica ... 14-05-2025

Source(s) of monetary or material Support: NWO Toptalent 2007 (Ellen Brunenberg;via TU/e)

Intervention

Keyword: deep brain stimulation, MRI, Parkinson S Disease, subthalamic nucleus

Outcome measures

Primary outcome

The primary study parameters of this study are qualitative: the visibility of the STN on anatomical MRI, the visibility of fiber bundles and thus the STN connectivity as can be derived from diffusion-weighted MRI.

Quantitative measures are the MRI image quality, represented as signal-to-noise ratio and contrast-to-noise ratio of the STN. We can analyze the spatial and angular resolution of the diffusion-weighted data. Concerning the functional MRI, the activation in the STN and other brain areas can be quantified using SPM2 software.

Secondary outcome

Not applicable.

Study description

Background summary

Parkinson's Disease patients suffer from severe motor symptoms. In an early stage of the disease, the patients are treated with medication. After long-term treatment however, this medication will often cause even more severe motor side-effects. For these patients, deep brain stimulation is an alternative therapy. Deep brain stimulation involves the implantation of electrodes that stimulate the brain at a high frequency. It is assumed that this alleviates the motor symptoms due to the inhibition of a hyperactive nucleus, the nucleus subthalamicus or STN.

The locomotion improves, but in 41% of the cases, cognitive side-effects occur after the operation. A group of 8% suffers from a depression, while 4% becomes manic. This can be explained by the fact that the STN does not only have a motor, but also a cognitive and an emotional function. Studies on monkey and rat brains have proven that three subparts of the STN can be indicated as well, that each have their own function.

Our hypothesis is that the cognitive side-effects can be avoided by a more specific stimulation of the motor part of the STN.

Study objective

The goal of the entire PhD project is to find the motor part of the STN using advanced image acquisition and image analysis. To reach this eventual goal, we first have to be able to visualize the STN as a whole. Published studies show only 2D-images with often vague contrast, made with just one of the possible protocols. Thus, our first goal is the verification and comparison of published protocols in three dimensions. Furthermore, we will investigate new scan protocols. The results of these experiments can be used immediately for a better planning and navigation for deep brain stimulation in the hospital.

The second objective is to distinguish the three different subparts of the STN. We will experiment with diffusion-weighted MRI to analyze the connectivity of the STN with other brain areas. We assume that the directions of the nerve tracts in the brain, derived from diffusion-weighted images, can be used for this purpose, because the different parts of the STN are each connect to different other areas, depending on the function.

Thirdly, we want to generate complementary information using functional MRI. We will map both the location of STN activation and the correlation in activation in the STN and other parts of the brain.

Eventually, the collection of all these data should lead to a more precise localization of the STN and its motor part preceding a deep brain stimulation procedure.

Study design

This study is just a pilot or feasibility study on the right protocols, using healthy volunteers.

Study burden and risks

The burden per subject comprises one visit to the radiology department, lasting

3 - Deep brain stimulation for Parkinson's Disease: a feasibility study on anatomica ... 14-05-2025

about 80 minutes, of which 30 minutes will be used for introduction and screening. Afterwards, five scans of in total 50 minutes will be made.

Because a metal screening will be done and no contrast agent will be injected, there is almost no risk for the subject.

Because of the very low risk and because the subject only sacrifices 80 minutes of time, the study seems justified, looking at its possible benefit. This benefit is the avoidance of cognitive side-effects of deep brain stimulation. Currently, many patients cannot undergo deep brain stimulation, only because the risk of side-effects is too large.

Contacts

Public Academisch Ziekenhuis Maastricht

Postbus 5800 6202 AZ Maastricht Nederland **Scientific** Academisch Ziekenhuis Maastricht

Postbus 5800 6202 AZ Maastricht Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

older than 18 years no known neurological deficits

Exclusion criteria

subject displays abnormalities (anatomically or due to artifacts) on MRI scan metallic prosthesis, neurostimulator or pacemaker in subject's body other contra indications for MRI

Study design

Design

Study type: Observational non invasive	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2008
Enrollment:	15
Туре:	Actual

Ethics review

Approved WMO	
Date:	11-07-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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 CCMO ID NL23489.068.08