Treatment in advanced Parkinson*s disease: continuous intrajejunal levodopa infusion versus deep brain stimulation; a feasibility study

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

Summary

ID

NL-OMON39084

Source
ToetsingOnline

Brief title
INVEST (INfusion VErsus STimulation) feasibility study

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease; Parkinson

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,Reserve De Bie AMC

Intervention

Keyword: Continuous Levodopa Infusion, Deep Brain Stimulation, Parkinson Disease

Outcome measures

Primary outcome

The main objective is the randomization rate, measured as the percentage of patients that agrees to be randomized to CLI or DBS out of all eligible patients.

Secondary outcome

For the cross-sectional study, the secondary outcome measure is a structured interview, qualitatively evaluating the reasons for declining randomization.

n the pilot-trial, we will assess the implementation of the research protocol including possible future outcome measures like the PDQ-39, UPDRS, ALDS, and EQ-5D, neuropsychological and psychiatric measures and costs.

Study description

Background summary

Neurologists and patients tend to choose more often for Continuous intrajejunal Levodopa Infusion (CLI) than Deep Brain Stimulation (DBS) for the treatment of advanced Parkinson*s disease (PD), although the efficacy of CLI is not convincingly demonstrated. Without direct comparative data, this situation will continue. A comparative study would provide a scientific basis for the treatment choice in advanced PD. We submitted an application with The Netherlands Organization for Health Research and Development (ZonMw) for funding of a larger comparative study of CLI and DBS. Although the committee considered the study design as good and the research question as relevant, the request was declined with the argument that strong patient preferences

regarding the fairly invasive procedures would affect inclusion negatively, to such an extent that the study would be not feasible. Since the influence of patient preference in this context is unknown, we propose a pilot trial to evaluate feasibility. This will give a strong argument as to whether a randomized comparative trial would be feasible.

Study objective

The primary objective of the proposed feasibility study is to determine the willingness of patients to be randomized to CLI or DBS. Furthermore it will serve as a pilot trial for a future larger randomized controlled trial. For this larger trial, that will only be carried out if feasibility has been confirmed, the objective is to determine whether CLI or DBS is a better therapy in advanced PD. The pilot-trial will give a detailled insight in the implementation of a possibile research protocol for the future larger study, including possible outcome measures.

Study design

The feasibility study will consist of two elements: a cross-sectional study assessing the willingness for randomization to CLI or DBS and a prospective, randomized, open label multicenter pilot-trial including the patients that are willing to be randomized. In the pilot-trial, patients will be randomized to CLI or DBS. For CLI treatment, a tube will be placed in the jejunum via a percutaneous endoscopic gastrostomy (PEG). This tube is connected to an external pump that delivers the levodopa-gel. For DBS treatment, 2 electrodes will be implanted in the brain. The electrodes are connected to an implanted pulse generator, which will be placed subcutaneously in the subclavian area.

Intervention

For CLI treatment, a tube will be placed in the jejunum via a percutaneous endoscopic gastrostomy (PEG). This tube is connected to an external pump that delivers the levodopa-gel. For DBS treatment, 2 electrodes will be implanted in the brain. The electrodes are connected to an implanted pulse generator, which will be placed subcutaneously in the subclavian area.

Study burden and risks

The study investigates the feasibility of a future larger study comparing CLI and DBS. Both treatments are currently available for advanced PD and both have a small risk of serious side effects.

Patients that are included in the cross-sectional study and do not want to participate in the pilot trail will be asked to complete a questionnaire on their motives to decline randomization. This is estimated to take 15 minutes.

For included patients that agree with randomization, the surplus in burden of study participation compared to the regular treatment consists of both more and more detailed assessment procedures. We estimate these extra procedures * consisting of filling in questionnaires and performing motor function assessments * take approximately 10 hours, including time to travel. This is a negligible risk according to the NFU (Nederlandse Federatie van Universitaire Medische Centra) criteria for human research.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-idiopathic PD with bradykinesia and at least two of the following signs; resting tremor, rigidity, and asymmetry;
-despite optimal pharmacological treatment at least one of the following symptoms: severe

response fluctuations, dyskinesias, painful dystonias, or bradykinesia;
-a life expectancy of more than two years.

Exclusion criteria

-age below 18 years;
-previous PD-neurosurgery (e.g. DBS, pallidotomy, thalamotomy);
-previous CLI (through a PEG-tube or Nasal Jejunal tube);
-Hoehn and Yahr stage 5 at the best moment during the day;
-a Montreal Cognitive Assessment score of 25 or less (MOCA; http://www.mocatest.org);
-psychosis;
-current depression despite optimal pharmacotherapy;
-contraindications for DBS surgery, such as a physical disorder making surgery hazardous;
-contraindications for PEG surgery and Duodopa;
-pregnancy, breastfeeding, and women of child bearing age not using a reliable method of contraception;
-inability to provide written informed consent;
-legally incompetent adults.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-03-2014
Enrollment:	59
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Duodopa
Generic name:	levodopa and carbidopa monohydrate intestinal gel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	22-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-03-2014
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
EudraCT	EUCTR2012-004643-69-NL
CCMO	NL41114.018.12