Infusion VErsus STimulation, a cost-effectiveness analysis of the treatment in advanced Parkinson's disease comparing Continuous Intrajejunal Levodopa Infusion to the traditional standard treetment Deep Brain Stimulation;

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

Summary

ID

NL-OMON50651

Source
ToetsingOnline

Brief title
INVEST (Infusion VErsus STimulation) study

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Parkinson's Disease

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Medtronic B.V.,Medtronic;verstrekker van DBS materiaal

Intervention

Keyword: Continuous Levodopa Infusion, cost-effectiveness, Deep Brain Stimulation, Parkinson Disease

Outcome measures

Primary outcome

The primary health economic outcomes of the randomized trial are the costs per unit on the PDQ-39 and the costs per QALY for the cost-effectiveness and cost-utility analyses respectively.

Secondary outcome

Secondary clinical outcomes are quality of life (PDQ-39), PD motor symptoms (UPDRS), dyskinesias (CDRS), 3-day motor symptom diary), adverse effects and complications, treatment failure, non-motor symptoms such as autonomic functions and sleep (Non Motor Symptom Checklist, Rotterdam Symptom Checklist), PD-medication, disability, functional health status (ALDS), patient and physician preferences, patient satisfaction, caregiver burden, neuropsychological and psychiatric assessment, stopping treatment, starting with the alternative than initially started treatment, and medical and non-medical care costs (iMCQ, iPCQ).

Study description

Background summary

Both Continuous intrajejunal Levodopa Infusion (CLI) and Deep Brain Stimulation (DBS) are accepted therapies for the treatment of advanced Parkinson*s disease (PD). Neurologists and patients tend to prefer the more expensive CLI although a scientific rationale is lacking. To determine the optimal treatment in advanced PD, a comparative study of CLI and DBS is warranted.

Study objective

The objective of the study is to realize an efficient allocation of resources to the available treatment options in advanced PD, while guaranteeing the highest standard of care.

Secondary objectives are
1) to quantify the need for and cost of healthcare and the health benefits in both groups
2) to assess the patients motor and non-motor symptoms, quality of life and daily functioning in both DBS and CLI
3) to register and compare adverse effects and complications in both groups and verify patients* and treating physicians* conceptions about the different treatments

Study design

Prospective, randomized, open label multicenter trial, with two additional patient preference treatment arms (*patient preference randomized trial*).

Intervention

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.

Study burden and risks

The study investigates the cost-effectiveness and cost-utility comparing CLI and DBS. Both treatments are currently available for advanced PD and both have a small risk of severe side effects. The surplus in burden of study participation compared to the regular treatment consists of both more and more

detailed assessment procedures. The additional time for these extra procedures * consisting of questionnaires and motor symptom assessments * is approximately 15 hours, including time to travel. Besides this small burden the study has no additional risk compared to standard practice, which constitutes a negligible risk according to the NFU (Nederlandse Federatie van Universitaire Medische Centra) criteria for human research.

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

- idiopathic Parkinson's Disease 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 dystonia or

bradykinesia;
-a life expectancy of at least two years.

Exclusion criteria

-age below 18 years
- previous PD-neurosurgery (e.g., DBS, pallidotomy, thalamotomy);
- previous CLI (through a PEG-tube or Nasal Jejuna| tube);
- Hoehn and Yahr stage 5 at the best moment during the day;
- dementia or indication for severe cognitive impairment, such as PD-CRS <65;
- psychosis;
- current depression;
- other, severely disabling condition;
- contraindications for DBS surgery, such as a physical disorder making surgery hazardous;
- contraindications for PEG surgery such as interposed organs, ascites and oesophagogastric varices, or for Duodopa;
- pregnancy, breastfeeding, and women of child bearing age not using a reliable method of contraception;
- No informed consent;
- legally incompetent adults.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-12-2014
Enrollment:	66
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:	28-11-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-12-2016
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-06-2020
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

ID: 21505
Source: NTR

Title:

In other registers

Register	ID
EudraCT	EUCTR2014.001501.32-NL
ClinicalTrials.gov	NCT02480803
CCMO	NL51240.018.14
OMON	NL-OMON21505