The INVEST study Treatment in advanced Parkinson’s disease: continuous intrajejunal levodopa INfusion VErsus deep brain STimulation.

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Continuous Intrajejunal Levodopa Infusion is not cost-effective compared to Deep Brain Stimulation

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

Summary

ID

NL-OMON21505

Source
NTR

Brief title
INVEST

Condition

- Movement disorders (incl parkinsonism)

Health condition

advanced Parkinson's disease, gevorderde ziekte van Parkinson

Research involving
Human

Sponsors and support

Primary sponsor:	ZonMw
Secondary sponsors:	Medtronic Europe
Source(s) of monetary or material Support:	ZonMw (Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie) MedTronic

Intervention

Explanation

Outcome measures

Primary outcome

The costs per unit on the PDQ-39 and the costs per QALY for the cost-effectiveness and cost-utility analyses respectively. The EQ-5D will be applied as the utility measure.

Secondary outcome

Secondary clinical outcomes are quality of life (PDQ-39 at baseline, 9 and 12 months), PD motor symptoms (MDS-UPDRS-score at baseline and 12 months), dyskinesias (CDRS at baseline and 12 months), 3-day motor symptom diary (at baseline and 12 months), non-motor symptoms such as autonomic functions and sleep (Non Motor Symptom Checklist, Rotterdam Symptom Checklist at baseline and 12 months), adverse effects and complications (at every visit), treatment failure (at every visit), stopping treatment, starting with the alternative than initially started treatment, PD-medication (at every visit), disability (Hoehn and Yahr stage at baseline and 12 months), functional health status (ALDS at baseline and 12 months), patient and physician preferences, patient satisfaction, caregiver burden, neuropsychological and psychiatric assessment at baseline and 12 months, and medical and non-medical care costs (iMCQ and iPCQ at every visit).

Study description

Background summary

Rationale: 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.

Hypothesis: We hypothesize that CLI is a more expensive therapy in advanced PD than DBS and that the surplus in costs is not cost-effective with regard to benefits for the patient and caregivers in quality of life, PD symptoms and adverse events.

Objective: To realize a cost-effective treatment strategy in advanced PD.

Study design: Prospective, randomized, open label multicentre trial, with two additional patient preference treatment arms (“patient preference randomized trial”).

Study population: Patients with PD who, despite optimal pharmacological treatment, have severe response fluctuations, dyskinesias, painful dystonia, or bradykinesia. A total of 66 patients will be randomized, at least 120 patients will be included in the patient preference arms.

Intervention: Patients will be randomized to DBS or CLI. 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. 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.

Main study parameters: There are 6 specified assessment visits: at baseline, and 1 week, 3, 6, 9, and 12 months after start of the study treatment. The primary health economic outcomes are the costs per unit on the PDQ-39 and the costs per QALY for the cost-effectiveness and cost-utility analyses, respectively. The EQ-5D will be applied as the utility measure. Among the secondary outcomes are neurological impairments, functional health, care use and perceptions of patients and neurologists regarding both treatments.

Study objective

Continuous Intrajejunal Levodopa Infusion is not cost-effective compared to Deep Brain Stimulation

Study design

1 week, 1 month, 3 months, 6 months, 9 months and 12 months after treatment

Intervention

Continuous Intrajejunal Levodopa Infusion (CLI) and Deep Brain Stimulation (DBS).

Contacts

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Eligibility criteria

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

- A Montreal Cognitive Assessment score of 25 or less (MOCA; http://www.mocatest.org);

- Psychosis;

- Current depression;

- 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 phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2014
Enrollment:	66
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO Date:	28-11-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

ID: 50651
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4753
NTR-old	NTR4881
CCMO	NL51240.018.14
EudraCT	2014-004501-32
ClinicalTrials.gov	NCT02480803
OMON	NL-OMON50651

Study results