INfusie VErsus STimulatie

Gepubliceerd: 03-11-2014 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Bewegingsstoornissen (incl. parkinsonisme)
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21505

Bron
NTR

Verkorte titel
INVEST

Aandoening

- Bewegingsstoornissen (incl. parkinsonisme)

Aandoening

advanced Parkinson's disease, gevorderde ziekte van Parkinson

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor:	ZonMw
Secundaire sponsoren:	Medtronic Europe
Overige ondersteuning:	ZonMw (Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie) MedTronic

Onderzoeksproduct en/of interventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Academisch Medisch Centrum
Afdeling Neurologie
Postbus 22660
J.M. Dijk
Amsterdam 1100DD
The Netherlands
020-5669111

Wetenschappelijk

Academisch Medisch Centrum
Afdeling Neurologie
Postbus 22660
J.M. Dijk
Amsterdam 1100DD
The Netherlands
020-5669111

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Fase onderzoek:	3
Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	19-12-2014
Aantal proefpersonen:	66
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Goedgekeurd WMO

Datum:	28-11-2014
Soort:	Eerste indiening
Toetsingscommissie:	METC Amsterdam UMC

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50651
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten