Transcutaneous port (T-Port) for gastrostomy use in combination with Duodopa.

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The primary objective of this test series will be to gain experience and provide long-term safety using a transcutaneous titanium port as an access port for gastrostomy (T-Port) in the context of Duodopa treatment of severely afflicted PD patients.

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

Summary

ID

NL-OMON30462

Source
ToetsingOnline

Brief title
T-Port and Duodopa

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: TransCutan AB
Source(s) of monetary or material Support: Ministerie van OC&W,Firma Solvay: het T-Portsysteem wordt betaald. Het Duodopa-systeem wordt door de zorgverzekeraar vergoed.

Intervention

Keyword: Duodopa, Parkinson's disease, T-Port

Outcome measures

Primary outcome

Safety:

To assess the safety and tolerability:

* Adverse event monitoring.

* Tolerability assessed by number of subjects who complete the 6 months of

treatment

* Acceptance of the T-Port by the patients

In addition:

• Physical examination, including weight.

• Vital signs systolic/diastolic blood pressure and pulse rate.

• Concomitant medication usage.

• Monitoring complications of the infusion device.

Utility:

Utility will be assessed using the UPDRS, TRS (treatment rating scale) and

PDQ-8

Secondary outcome

NvT

Study description

Background summary

Transcutaneous Port (T-Port) for Gastrostomy Use in Combination with Duodopa®

This is a 6 month, open-label, study of the safety and tolerability of implanting a T-Port for gastrostomy in approximately 10 patients receiving Duodopa, who have been shown to have levodopa-responsive Parkinson's disease, with persistent severe motor fluctuations despite optimized treatment with available Parkinson medicinal products.

Duodopa is delivered to the upper intestine through a catheter inserted via percutaneous endoscopic gastrostomy (PEG). Gastrostomy will be aided with use of the transcutaneous titanium port (T-Port). The Duodopa infusion system consists of a suspension which is dispensed in medication cassette reservoirs designed to be connected to a portable pump. The contents of the medication cassette reservoir are delivered via continuous administration over a sixteen hour period. Additional bolus doses can be given to address immediate medical needs.

The reference therapy will be the PEG-duodenal/jejunal tube applied which until recently is the standard Duodopa approach. The disadvantages of the PEG methods are mainly: leakage problems, dislocation of tube into the stomach, blocking problems. Also cosmetic and handling disadvantages are mentioned by the patients. The dose of Duodopa and the administration by the pump will be identical in the T-Port system.

Study objective

The primary objective of this test series will be to gain experience and provide long-term safety using a transcutaneous titanium port as an access port for gastrostomy (T-Port) in the context of Duodopa treatment of severely afflicted PD patients.

Study design

This is an open study assessing the long-term safety and utility of a new gastrostomy access port for use with Duodopa, in patients in whom a positive test of the clinical response was already conducted with Duodopa administered via a nasoduodenal tube. Only those PD patients are eligible for the T-Port system who on clinical grounds will be proposed to have Duodopa therapy.

Study burden and risks

The burden of the project is almost identical to the conventional PEG duodenum therapy. In addition the patient has to wait 2 weeks before the Duodopa

infusion can be started instead of immediate infusion after the PEG tube has been placed.

Also the patient has to come to the out-patient clinic 6 times during 6 months after implantation of the T-Port. After PEG tube positioning the patient usually has to return to the out-patient clinic only 3 or 4 times within the first 6 months, provided no complications are encountered.

Risks: local hematoma or infection in the abdominal wall.

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

Clinical diagnosis of advanced Parkinson's disease. On/off phenomena leading to severe

disability which can not be regulated by the normal oral drug schemes. A clinical indaction for duodenum Duodopa tretament should have been made by the treating physician.

Exclusion criteria

non-responsiveness to levodopa substitution therapy. Deformities abdominal wall.

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Titanium T-Port
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL16049.042.07
Other	Nog niet bekend.