Effectiveness of inhaled levodopa in Parkinson's disease

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22984

Source
NTR

Health condition

Parkinson's disease
Ziekte van Parkinson

Sponsors and support

Primary sponsor: Department of Pharmaceutical Technology and Biopharmacy, Faculty of Mathematics and Natural Sciences, University of Groningen
Source(s) of monetary or material Support: Parkinson Vereniging

Intervention

Outcome measures

Primary outcome

Time until maximum effect on motor function (maximum change from baseline), determined by the MDS-UPDRS III test scores 3.3 Rigidity, 3.4 Finger tapping, 3.9 Arising from chair, and 3.10 Gait.

Secondary outcome

Pharmacokinetic:

Maximum levodopa concentration in plasma(Cmax).

Time to maximum concentration (Tmax).

Area under the concentration time (minutes) curve at 0-180 min (AUC0-180) after administration of the dose

Pharmacodynamic:

Finger tap count in 30 seconds (3.4 Finger tapping).

The time it takes the patient to get up from a chair, walk 10 meters, turn around and walk back 10 meters (3.9 and 3.10 combined in timed up-and-go test).

Study description

Background summary

Countries of recruitment: The Netherlands

Study objective

Inhaled levodopa provides more rapid symptom relief than orally administered levodopa

Study design

Time points motor function tests: t = -1, 10, 20, 30, 40, 50, 60, 75, 90 min

Time points blood sampling: t = -1, 5, 10, 15, 20, 30, 45, 60, 75, 90, 180 min

Intervention

Inhalation of 90 mg levodopa

Oral administration of 100/25 mg orodispersible tablet levodopa/benserazide

Contacts

Public

RVE klinische farmacie
Van Swietenplein 1
Postbus 30033

M. Luinstra
Groningen 9700 RM
The Netherlands
050-5245771
Scientific
RVE klinische farmacie
Van Swietenplein 1
Postbus 30033

M. Luinstra
Groningen 9700 RM
The Netherlands
050-5245771

Eligibility criteria

Inclusion criteria

Diagnosed with Parkinson’s disease according to the UK Parkinson’s Disease Society Brain Bank Clinical Diagnostic Criteria;

At least 18 years of age;

Predictable off periods;

Recognisable off periods for themselves and others;

Sufficiently large (measurable) difference between on and off state (at least 10 points on the UPDRS III scale);

At least 2 years of levodopa use;

Morning levodopa dose equivalent to 100 mg levodopa;

Able to perform spirometry;

Signed informed consent.

Exclusion criteria

Cognitive dysfunction, which precludes good understanding of instructions and/or informed consent;

Current treatment with apomorphine or duodopa by pump;

Severe off periods during the night;

Current or past experience with depression/depressed mood;

Known symptomatic orthostatic hypotension;

Active pulmonary disease;

Pregnancy or breast-feeding.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2018
Enrollment:	9
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL6876
NTR-old	NTR7054
Other	Regionale Toetsingscommissie Patientgebonden Onderzoek Leeuwarden : RTPO 1019

Study results

Summary results
Can Patients with Parkinson’s Disease Use Dry Powder Inhalers during Off Periods? M. Luinstra, A. W. F. Rutgers, H. Dijkstra et al. Published: July 14, 2015. DOI: 10.1371/journal.pone.0132714

A levodopa dry powder inhaler for the treatment of Parkinson's disease patients in off periods. M. Luinstra, F. Grasmeijer, P. Hagedoorn et al. Eur J Pharm Biopharm. 2015 Oct 7. pii: S0939-6411(15)00404-X. doi: 10.1016/j.ejpb.2015.10.00