Inhalation of Levodopa in Parkinson's disease

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25573

Source
Nationaal Trial Register

Brief title
ParkinsonDPI-2

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 supports part of this research.

Intervention

Outcome measures

Primary outcome

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 (related to the actual dose administered, weighed dose minus remained dose in inhaler after inhalation).

Secondary outcome

Absorption rate constant (Ka) of levodopa after pulmonary administration.

Terminal elimination half life (T1/2el) of levodopa after pulmonary administration.

Decrease of FEV1 in percentage measured by spirometry (at predose, 35 and 100 minutes after administration.

Number of participants with adverse events (both spontaneously reported and reported as a result of questioning by the researcher.

Study description

Background summary

-

Study objective

A more rapid rise of the levodopa plasma level after inhalation compared to oral administration of levodopa.

Study design

3 visits: at least 1 week between 2 visits and all visits within 6 months.

Intervention

First visit: inhalation of 30 mg levodopa inhalation powder.

Second visit: inhalation of 60 mg levodopa inhalation powder.

Third visit: regular oral levodopa medication.

During all three visits, the participants undergo spirometry (lung function testing) and multiple bloodsamples are drawn.

Contacts

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Eligibility criteria

Inclusion criteria

Signed informed consent.

Diagnosed with Parkinson’s disease

At least 18 years old.

Currently on stable Parkinson’s disease levodopa regimen.

Require levodopa containing medication regimen with a maximum of 4 administrations a day.

Able to perform spirometry

Exclusion criteria

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

Pregnant or breast feeding.

Active pulmonary disease.

Patients with known symptomatic orthostatic hypotension.

The use of COMT inhibitors and/or MAO-B inhibitors.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2016
Enrollment:	8
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-10-2015
Application type:	First submission

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	NL5326
NTR-old	NTR5435
Other	- : ParkinsonDPI-2

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.2015.10.003