Dry powder inhalation in patients with Parkinson’s disease.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24879

Source
NTR

Health condition

Ability of a Parkinson’s patient to use the inhaler correctly during off periods.

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: initiator = sponsor

Intervention

Outcome measures

Primary outcome

The parameter that describes whether or not a Parkinson’s patient is capable of using the inhaler correctly is the pressure drop (s)he creates over the inhaler upon inhalation.

Secondary outcome

Peak and mean inspiratory flow rate (PIFR and MIFR).
Acceleration towards peak inspiratory flow rate (flow increase rate: FIR).

Inhaled volume.
Total inhalation time.

Study description

Background summary

The development of a dry powder inhaler (DPI) that suits the needs of Parkinson’s patients, based on their inspiratory capacities, is essential. In this study, we will investigate the applicability of dry powder inhalation in Parkinson’s patients, in order to enable us to develop a DPI specifically for this patient group, by testing if they can generate a sufficiently large airflow and volume through the test inhaler theoretically necessary to disperse a medicinal powder and transport the aerosol into the lower airways during an off period.

Recruiting will take place in The Netherlands

Study objective

The development of a dry powder inhaler (DPI) that suits the needs of Parkinson’s patients, based on their inspiratory capacities, is essential. In this study, we will investigate the applicability of dry powder inhalation in Parkinson’s patients, in order to enable us to develop a DPI specifically for this patient group, by testing if they can generate a sufficiently large airflow and volume through the test inhaler theoretically necessary to disperse a medicinal powder and transport the aerosol into the lower airways during an off period.

Study design

Pressure drop: Time point: during testing. The study will be conducted with an instrumented test inhaler with exchangeable air flow resistances. The device is provided with a pressure drop meter that records the pressure drop that is generated when the patient inhales through it. The pressure drop meter is linked to a computer equipped with software that calculates from the pressure drop the inspiratory flow rate as function of the inhalation time. Various relevant parameters can be derived from this curve, such as inhaled volume, total inhalation time and peak inspiratory flow rate.

Intervention

testing if they can generate a sufficiently large airflow and volume through a test inhaler.

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

Predictable off periods.

Recognizable off periods for themselves and others.

At least 2 years of levodopa use.

Signed informed consent.

Diagnosed with Parkinson’s disease according to the UK Parkinson’s disease society Brain Bank Clinical Diagnostic Criteria

Exclusion criteria

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

Current treatment with apomorphine or duodopa by pump.

Any chronic pulmonary disease; (asthma, copd, pulmonary fibrosis, pulmonary emphysema, pulmonary gas diffusion disorders, etc).

Lung cancer or a history of lung cancer (if not cancer free for at least 5 years).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2013
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion

Date:	08-10-2013
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	NL4036
NTR-old	NTR4202
Other	RTPO 906 : 45210.099.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A