Investigation of the applicability of dry powder inhalation in patients with Parkinson*s disease.

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To determine if a Parkinson*s patient can operate a test inhaler correctly during off periods, by testing if they can generate a sufficiently large airflow and volume through the test inhaler theoretically necessary to disperse a medicinal powder...

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

Summary

ID

NL-OMON38957

Source
ToetsingOnline

Brief title
Dry powder inhalation in patients with Parkinson*s disease.

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinsons disease; Parkinson

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Inhalation, Parkinson's

Outcome measures

Primary outcome

the main study parameter is the ability of a Parkinson*s patient to use the inhaler correctly during off periods. 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. For the Twincer* a pressure drop of at least 2 kPa is needed, but the target pressure drop is 4 kPa.

Secondary outcome

NA

Study description

Background summary

Because of limited treatment options with a very rapid onset for Parkinson*s disease patients in the off period, there is a need for the development of rapid onset options to administrate levodopa (rescue therapy), like a pulmonary formulation of levodopa. Rescue therapy is used on an acute, as-needed basis to return patients to an on state when they are experiencing an off state. Rescue therapy aims at a rapid return to an on state in patients with wearing off or patients with early morning akinesia.

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.

Study objective

To determine if a Parkinson*s patient can operate a test inhaler correctly during off periods, 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

The study is a non-therapeutic observational study in which the applicability of dry powder inhalation in Parkinson*s patients will be investigated. The study will be conducted with an instrumented test inhaler. The test inhaler concept is a dummy, without any drug substance or excipient. It is equipped with a pressure drop meter to record the inhalation curve of the patient.

In order to be able to measure during an off period, patients will be asked to postpone a dose of levodopa until they become off. As soon as the patient starts feeling off, explanation of the test procedure will be started. Because becoming off is not one fixed point in time but will take a while, a 15 minute waiting period before start of the inhalation test will be taken. During this waiting period, the researcher will explain the test procedure. The patient will receive instructions on how to use the test inhaler. The instructions will be given orally and partly be demonstrated by the instructor, partly be visualised by photographs and recordings of generated flow curves on a computer screen. 15 minutes after the patients started to feel off, a motor function examination (conform UPDRS III) will be performed. As soon as the UPDRS III is greater than or equal to 30, the inhalation test will be started. After the patient finished the test inhalations, the patient will take his/her levodopa.

Study burden and risks

The inhaler used is a specially designed dummy without drug or excipient, so the Parkinson*s patient will not inhale anything but air during the test. The burden is minimal as the procedures are limited to the performance of a couple of inhalations (maximum 10). Per Parkinson*s patient, the test is limited to one test moment that lasts maximally 30 minutes per test moment. This observational study has no specific benefits for the participating Parkinson*s patients. Only when performed in this population, information on the inspiratory capacities of Parkinson*s patients can be obtained. Since all patients included are familiar with frequent off episodes, no new discomfort compared to other off episodes is expected. The timeframe between the morning levodopa dose and the postponed levodopa dose is expected to be shorter than the levodopa free period during the night. The patients are used to a levodopa free period and the effect of this levodopa free period on their motor function.

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

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
Age 18 or older.

Exclusion criteria

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

Current treatment with apomorphine or duodopa by pump.
Any active pulmonary disease.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2014
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	18-12-2013
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO

Date:	11-09-2014
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL45210.099.13