Use of the Cyclops dry powder inhaler by patients with Parkinson's disease after inhalation instruction.

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The primary objective is to investigate whether Parkinson*s patients are able to produce an optimal inhalation technique for the Cyclops® inhaler in their home situation after first and second inhalation instruction. The secondary objective is to...

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

Summary

ID

NL-OMON55067

Source
ToetsingOnline

Brief title
Use of the Cyclops by Parkinson's patients.

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Parkinson's disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cyclops, Inhalation, Parkinson's, Use

Outcome measures

Primary outcome

The main study parameter is to investigate whether Parkinson*s patients are able to reproduce an optimal inhalation technique for the Cyclops® inhaler by measuring the pressure drop (kPa), breath hold time (sec.) and inhaled volume (L) after first and second inhalation instruction.

Secondary outcome

The secondary study parameter is to investigate whether Parkinson*s patients perform the correct steps in accordance with the patient instruction card with the Cyclops® inhaler after first and second inhalation instruction.

Study description

Background summary

Very limited treatment options are available with a rapid onset to counter off periods in Parkinson*s disease patients. Therefore, the development of rapid onset levodopa formulations is warranted, for which an inhalable formulation of levodopa is being investigated. It is important to know whether Parkinson*s patients used the inhalable formulation correctly in their home situation a couple weeks after instruction. Since the inhalable formulation will only be used during off periods, the frequency of which can vary from a few times a week to a few times a day (opposed to inhalation medication for pulmonary disorders that are used daily).

Study objective

The primary objective is to investigate whether Parkinson*s patients are able to produce an optimal inhalation technique for the Cyclops® inhaler in their home situation after first and second inhalation instruction. The secondary objective is to investigate if Parkinson*s patients understand the patient

instruction card and follow the steps correctly.

Study design

Non-therapeutic observational study.

Study burden and risks

The inhaler that will be used is a dummy without drug or excipient, so the Parkinson*s patients will not inhale anything but air during the test and during the exercises. The burden is minimal as the procedure is limited to practice one inhalation per day.
Per Parkinson*s patient, the study is limited to three test moments 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 Parkinson*s patients can be obtained.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Diagnosed with Parkinson's disease by a nerologist;
- At least 18 years of age;
- Signed informed consent.

Exclusion criteria

- Not able to understand inhalation instruction (within a maximum of 30 minuten).
- Previously participated in the Parkinson DPI-1, DPI-2 or DPI-3 studie (prior knowledge of the inhalation maneuver);
- Active pulmonary disease.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	09-12-2019
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	21-12-2020
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	20-12-2021
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	NL69706.099.19

Study results

Date completed:	09-04-2022
Actual enrolment:	20