Usability of Levodopa Cyclops* compared to INBRIJA® during an off episode in Parkinson*s disease patients

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The primary objective is to determine whether there is a difference in the capability of the patients to successfully follow the instructions of both the Levodopa Cyclops* and the INBRIJA® inhaler during an off episode, based on the instruction...

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

Summary

ID

NL-OMON53590

Source
ToetsingOnline

Brief title
Usability of Levodopa Cyclops* vs INBRIJA® in 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, Inbrija, Inhalation, Parkinson

Outcome measures

Primary outcome

The main study parameter is to investigate whether PD patients perform the correct steps in line with the instruction card of respectively the Levodopa Cyclops* or INBRIJA® inhaler after the primary inhalation instructions and to collect information about problems experienced during the inhalation maneuver.

Secondary outcome

The secondary study parameter is to collect information about the opinion of PD patients regarding the ease-of-use and convenience of the different steps of the inhaler user maneuver of both inhalers.

Study description

Background summary

Currently there is one Levodopa inhaler on the market, the INBRIJA® inhaler. When looking at the user instructions for the INBRIJA®, multiple steps are necessary including preparing and cleaning the inhaler. The Levodopa Cyclops* inhaler also requires steps to be ready-for-use, however there are less steps required to reach this *ready-for-use* state. This is mainly because the medicine (Levodopa) is already prefilled in the inhaler. Moreover, the Levodopa Cyclops* is a single-use inhaler and cleaning steps are not necessary. Since both inhalers should be used during off episodes, there might be a preference for one inhaler over the other due to the instructions. An off episode might impair the ability and length to successfully operate an inhaler due to mental or mobility issues.

Study objective

The primary objective is to determine whether there is a difference in the capability of the patients to successfully follow the instructions of both the

Levodopa Cyclops* and the INBRIJA® inhaler during an off episode, based on the instruction cards of both inhalers.
The secondary study parameter is to collect information about the opinion of PD patients regarding the ease-of-use and convenience of both inhalers by filling in a questionnaire.

Study design

A crossover non-therapeutic observational study.

Study burden and risks

The inhalers that will be used are dummy inhalers without drug of excipient, so the Parkinson's patients will not inhale anything but air during the test. The burden is minimal as the tests consists of performing an inhalation maneuver during an off episode and filling in the questionnaire. Per Parkinson's patient, the study is limited to one test moment which takes approximately 2 hours. This observational study has no specific benefits for the participating Parkinson's patients. Performing the test in this population is necessary to obtain information on Parkinson's patients.

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 neurologist;
- At least 18 years of age;
- Regularly suffering from predictable off episodes despite PD medication;
- Recognizable off episodes for themselves and others;
- Signed informed consent.

Exclusion criteria

- Not able to understand an inhalation instruction of either the Levodopa Cyclops* or the INBRIJA® (within a maximum of 20 minutes of explanation per inhaler);
- Cognitive dysfunction, which precludes good understanding of instructions and/or informed consent;
- Previously participated in the Parkinson DPI-1, DPI-2, DPI-3, DPI-4 or DPI-5 study (prior knowledge of the inhalation maneuver of the Levodopa Cyclops*)
- Having experience with using the INBRIJA® inhaler.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-02-2024

Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	Cyclops inhaler
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-02-2023
Application type:	First submission
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	NL82043.099.23