

# Use of the Cyclops® by Parkinson's patients

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON22676

### Source

Nationaal Trial Register

### Brief title

DPI-5

### Health condition

Parkinson's disease

## Sponsors and support

**Primary sponsor:** Martini Hospital Groningen

**Source(s) of monetary or material Support:** initiator = sponsor

## Intervention

## 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

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 design

At the first appointment (T=0) the patient receives an inhalation instruction with a dummy Cyclops® inhaler. The instructions will be given verbally and partly be demonstrated by the instructor, partly be visualised by photographs on the patient instruction card and recordings of generated flow curves on a computer screen.

At the second appointment (T=1), two weeks ( $\pm 2$  days) after the first appointment and at the third appointment (T =2), four weeks ( $\pm 4$  days) after the second appointment, patients will be visited by the investigator and will be asked to demonstrate their inhalation technique with a dummy Cyclops® equipped with a pressure drop meter.

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

- Diagnosed with Parkinson's disease by a neurologist;
- 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

Intervention model: Other

Allocation: Non controlled trial

**Control:** N/A , unknown

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-01-2020  
Enrollment: 20  
Type: Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion  
Date: 21-10-2019  
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	NL8102
Other	RTPO 1081 : 69706.099.19

## Study results

**Summary results**

Can Patients with Parkinson's Disease Use Dry Powder Inhalers during Off Periods? Luinstra M, Rutgers AW, Dijkstra H, Grasmeyer F, Hagedoorn P, Vogelzang JM, Frijlink HW, de Boer AH. PLoS One. 2015 Jul 14;10(7):e0132714.