Use of the Cyclops® by Parkinson’s patients

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22676

Bron
Nationaal Trial Register

Verkorte titel
DPI-5

Aandoening

Parkinson's disease

Ondersteuning

Primaire sponsor: Martini Hospital Groningen
Overige ondersteuning: initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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).

Onderzoeksopzet

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 (± 2 days) after the first appointment and at the third appointment (T =2), four weeks (± 4 days) after the second appointment, patients will be 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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-10-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8102
Ander register	RTPO 1081 : 69706.099.19

Resultaten

Samenvatting resultaten

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