Inhaled glycopyrronium on excessive sialorrhea and drooling

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	-

Summary

ID

NL-OMON27582

Source
NTR

Brief title
INGESD

Health condition

Sialorrhea, drooling, Parkinson Disease.
Speekselvloed, kwijlen, Ziekte van Parkinson

Sponsors and support

Primary sponsor: Medisch Spectrum Twente, Enschede
Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

The safety and tolerability of glycopyrronium inhalation powder in patients diagnosed with sialorrhea and parkinson disease, measured in adverse events and other special events that occur.

Secondary outcome

Het mean difference in drooling between different dosing regimes and the patient preference.

Study description

Background summary

Objective: The primary objective is to investigate the safety and tolerability of inhalation of glycopyrronium inhalation powder using different dosing regimens. The second objectives are to determine the decrease in drooling by using different dosing regimens of glycopyrronium inhalation powder and to investigate the preferred method of treatment by patients.

Study design: A 5-week dose finding study to determine the optimal dose for glycopyrronium inhalation use in PD patients suffering from sialorrhea.

Study population: Patients, age 18 or older, diagnosed with Parkinson’s disease with moderate to severe sialorrhea.
Intervention: Following a baseline week, each participant will use glycopyrronium inhalations during four weeks. Every week the dosing regimen change: starting with one time daily inhalation of 44 µg glycopyrronium, followed by two time daily inhalation of 44 µg glycopyrronium, then a three time daily inhalation of 44 µg glycopyrronium, and during week 4 participants can use glycopyrronium on demand (zero to four times a day).

Main study parameters/endpoints: The primary endpoint is the determination of the safety and tolerability of glycopyrronium inhalations in PD patients with sialorrhea. The secondary endpoints are to determine mean difference in loss of saliva between dosing regimens and baseline week and to investigate the preferred method of treatment by patients.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Drooling can have a major impact on parkinsonian patients. The current standard-of-care oral solution of glycopyrronium is suboptimal for some patients. Therefore research is needed in this population.

Study objective

Glycopyrronium solution is used in patients suffering from sialorrhea and Parkinson Disease. The solution isn't sufficient enough for all patients due to to much effect or no effect at all. Glycopyrronium inhalation powder is used in patients with COPD, a common side effect is dry mouth. This gives us the hypothesis that it can be used in patients suffering from sialorrhea.

Study design

T0: Inclusion
T1: week with once daily use of glycopyrronium

T2: week with twice daily use of glycopyrronium

T3: week with three times a day use of glycopyrronium

T4: week with ondemand use of glycopyrronium with a maximum of 4.

Intervention

The participant will use 4 different dosing regimes of glycopyrronium inhalation powder. Three times a day a drooling score must be filled. Patients must record adverse events and other special events that occur during the use of the inhalation powder. after the 3rd week of treatment a patient preference questionaire must be answered.

Contacts

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Eligibility criteria

Inclusion criteria

Diagnosed with Parkinson disease

Moderate to severe sialorrhea, defined as a minimum of 4 of the Mier scale

Age > 18 years

Able to fill the scoring table (or the partner/carer must be able to)

Exclusion criteria

Hypersensitivity to glycopyrronium or other excipients

Use of medication with known anticholinergic effects.

Study design

Design

Intervention model: Other
Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-12-2016
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	NL6076
NTR-old	NTR6223
Other	: METC: P16-23.

Study results