The effect of INhaled Glycopyrronium bromide on Excessive Sialorrhea and Drooling in Parkinson disease: a dose finding study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Salivary gland conditions
Study type	Interventional

Summary

ID

NL-OMON45524

Source
ToetsingOnline

Brief title
Inhaled glycopyrronium on excessive sialorrhea and drooling (INGESD)

Condition

- Salivary gland conditions
- Movement disorders (incl parkinsonism)

Synonym
Sialorrhea and drooling

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Onderzoeksgelden van de RVE-en neurologie en klinische farmacie

Intervention

Keyword: Drooling, Glycopyrronium, Inhalation, Sialorrhea

Outcome measures

Primary outcome

The primary endpoint is the determination of the safety and tolerability of

glycopyrronium inhalations in PD patients with sialorrhea.

Secondary outcome

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.

Study description

Background summary

Sialorrhea is reported in up to 75 percent of PD patients. Physical and psychosoclal complications of sialorrhea range from mild and inconvenient symptoms to severe problems that can have a significant negative Impact on quality of life. Glycopyrronium solution is prescribed to decrease sialorrhea in patients with Parkinson's Disease. The solution must be ingested thrice a day. Arbouw et al proved this solution is effectlve In Parkinsonian patients who suffer from sialorrhea. There are also patients who don't experience any benefits from using the glycopyrronium solution. This could be explained because the gastro-intestinal tract in PD-patients might be affected, resulting in poor absorption of the solution. There are also patients who experience severe side effects, like dry mouth, which ultimately leads to discontinuation. In 2013 glycopyrronium was released as an inhalation powder for patients who suffer from chronic obstructive pulmonary disease. A common side effect that was seen during clinical research was a dry mouth. This side effect could be

usefull in patients with sialorrhea. During advanced disease patients experience off-periods unexpected. This can come together multiple episodes of sialorrhea a day.

Study 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.

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 50 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).

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnosed with Parkinson disease
Moderate to severe sialorrhea, defined as a minimum of 4 on 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

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2017
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Seebri
Generic name:	glycopyrronium bromide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	07-04-2017
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
EudraCT	EUCTR2016-004162-26-NL

Register	ID
CCMO	NL59782.044.17
Other	nnb