The effect of glycopyrronium bromide on hypersalivation in patients with Parkinson's disease: a randomised, cross-over, double-blind, placebo controlled trial.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON30532

Source
ToetsingOnline

Brief title
Glyspar study

Condition

- Movement disorders (incl parkinsonism)

Synonym
drooling, Hypersalivation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Ziekenhuis

Intervention

Keyword: Glycopyrronium, Hypersalivation, Parkinson's disease

Outcome measures

Primary outcome

Percentage of patients with a decrease of 3 points on the hypersalivation score

(on a scale from 1-9).

Secondary outcome

The difference in mean improvement on the hypersalivation score between the two

groups. Furthermore, the difference in reported adverse events will be

analysed.

Study description

Background summary

75% of patients with Parkinson's disease (PD) do suffer from hypersalivation. There are several symptomatic treatments for hypersalivation by decreasing the amount of water in saliva. Until now there is not a registered drug available in the treatment of hypersalivation. Most drugs used have disadvantages, such as central side effects. Glycopyrroniumbromide is a quartenair anticholinergic drug, that does only slightly pass the blood-brain barrier. The chance of central side effects is therefore lower. Formerly, there was a glycopyrroniumbromide injection available for the treatment of hypersalivation in patient undergoing surgery under anesthesia. This product was withdrawn because of commercial reasons in 2003. Neurologist in hospital Medisch Spectrum Twente have a good experience with oral glycopyrroniumbromide. However, the effect of oral glycopyrroniumbromide on hypersalivation has never been proved in patients with PD. Positive effects have been found with oral glycopyrroniumbromide in other patients with hypersalivation (e.g. patients

with cerebral palsy).

Study objective

The aim of this study is to prove the efficacy of 3 times daily 1 mg glycopyrronium bromide versus placebo in patients with PD with hypersalivation. Furthermore, the safety of glycopyrronium bromide used in the mentioned dosage will be further evaluated. In addition, the aim is to perform a pharmacogenetic analysis with these data within the purpose of this study.

Study design

This is a randomised, double-blind, placebocontrolled, cross-over study. It will take 5 weeks per patient. In week 1 there are baseline measurements, in week 2 glycopyrroniumbromide or placebo will be taken, in week 3 there are new baseline measurements, in week 4 cross-over glycopyrroniumbromide or placebo will be taken. The final visit will be in week 5. Patients score the extent of hypersalivation three times a day on a daily basis (scale from 1-9).

Intervention

Cross over design: In week 2 glycopyrroniumbromide (3 times 1mg=5ml daily) or placebo (3 times 5ml daily). In week 4 cross-over glycopyrroniumbromide (3 times 1mg=5ml daily) or placebo (3 times 5ml daily).

Study burden and risks

The main risks are the adverse effects of glycopyrroniumbromide. In trials with orally used glycopyrroniumbromide the adverse effects were mainly: dry mouth, miction problems, nausea and nervosity. The blood collection may result in a bruce.

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

- Patients with Parkinson's disease
- Age >=18 years
- Hypersalivation score >=5 (on a scale from 1-9)
- Patient or family is able to score the extent of hypersalivation

Exclusion criteria

- Hypersensitivity to glycopyrronium bromide, sorbic acid or saccharin sodium
- Myasthenia gravis
- Tachycardia
- Coronary insufficiency
- Glaucoma
- Pylorus stenosis
- Paralytic ileus
- Prostate hypertrophy
- Pregnancy or lactation

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2007
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	N.v.t.
Generic name:	Glycopyrronium bromide

Ethics review

Approved WMO Date:	13-11-2006
Application type:	First submission
Review commission:	METC Medisch Spectrum Twente (Enschede)
Approved WMO Date:	15-02-2007
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	EUCTR2006-005596-18-NL
CCMO	NL14912.044.06