The effect of glycopyrroniumbromide on hypersalivation in patients with Parkinson's disease: a randomised, cross-over, doubleblind, placebocontrolled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20228

Source
NTR

Brief title
Glyspar study

Health condition

Parkinsonian patients with hypersalivation

Sponsors and support

Primary sponsor: M.E.L. Arbouw,
Hospital Medisch Spectrum TwenteDepartment of clinical pharmacy
P.O. Box 50.000
7500 KA Enschede
The Netherlands
Source(s) of monetary or material Support: No funding obtained.

Intervention

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

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. 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).

Study objective

The aim of this study is to prove the efficacy of 3 times daily 1 mg glycopyrronium bromide admixture versus placebo admixture 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.

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).

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with Parkinson's disease;

2. Age >=18 years;

3. Hypersalivation score >=5 (on a scale from 1-9);

4. Patient or family is able to score the extent of hypersalivation.

Exclusion criteria

1. Hypersensitivity to glycopyrronium bromide, sorbic acid or saccharin sodium;

2. Myasthenia gravis;

3. Symptomatic tachycardia;

4. Coronary insufficiency;

5. Heart rythm disorders;

6. Glaucoma;

7. Pylorus stenosis;

8. Paralytic ileus;

9. Prostate hypertrophy;

10 Patients using potassiumchloride tablets, oral digoxin or oral corticosteroids;

11. Kidney function disorders;

12. Pregnancy or lactation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2007
Enrollment:	24
Type:	Actual

Ethics review

Positive opinion

Date:	24-01-2007
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	NL848
NTR-old	NTR862
Other	: APOMST001
ISRCTN	ISRCTN28592111

Study results

Summary results
N/A