

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

Submission date 08/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/01/2021	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

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

Acronym

Glyspar study

Study objectives

The aim of this study is to prove the efficacy of three times daily 1 mg glycopyrronium bromide admixture versus placebo admixture in patients with Parkinson's Disease (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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, placebo-controlled, cross-over group, double blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Parkinsonian patients, hypersalivation

Interventions

Week one: baseline measurements

Week two: glycopyrronium bromide (three times 1 mg [5 ml] daily) or placebo (three times 5 ml daily) will be taken

Week three: new baseline measurements

Week four: cross-over glycopyrronium bromide (three times 1 mg [5 ml] daily) or placebo (three

times 5 ml daily) will be taken

Week five: final visit

Patients score the extent of hypersalivation three times a day on a daily basis (scale from one to nine).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Glycopyrronium bromide

Primary outcome measure

Percentage of patients with a decrease of three points on the hypersalivation score (on a scale from one to nine).

Secondary outcome measures

The difference in mean improvement on the hypersalivation score between the two groups. Furthermore, the difference in reported adverse events will be analysed.

Overall study start date

01/02/2007

Completion date

01/01/2009

Eligibility

Key inclusion criteria

1. Patients with Parkinson's disease
2. Aged more than or equal to 18 years
3. Hypersalivation score more than or equal to five (on a scale from one to nine)
4. Patient or family is able to score the extent of hypersalivation

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Total final enrolment

23

Key exclusion criteria

1. Hypersensitivity to glycopyrronium bromide, sorbic acid or saccharin sodium
2. Myasthenia gravis
3. Symptomatic tachycardia
4. Coronary insufficiency
5. Heart rhythm disorders
6. Glaucoma
7. Pylorus stenosis
8. Paralytic ileus
9. Prostate hypertrophy
10. Patients using potassium chloride tablets, oral digoxin or oral corticosteroids
11. Kidney function disorders
12. Pregnancy or lactation

Date of first enrolment

01/02/2007

Date of final enrolment

01/01/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Hospital Medisch Spectrum Twente

Enschede

Netherlands

7500 KA

Sponsor information

Organisation

Hospital Medisch Spectrum Twente (The Netherlands)

Sponsor details

Department of Clinical Pharmacy

P.O. Box 50000

Enschede

Netherlands
7500 KA

Sponsor type

Hospital/treatment centre

Website

<http://www.ziekenhuis-mst.nl/>

ROR

<https://ror.org/033xvax87>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital Medisch Spectrum Twente (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/04/2010	15/01/2021	Yes	No