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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

Registration date
08/02/2007

Overall study status
Completed

Last Edited
15/01/2021

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

APOMST001, NL848, NTR862

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

24

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