

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

Gepubliceerd: 24-01-2007 Laatste bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20228

Bron

NTR

Verkorte titel

Glyspar study

Aandoening

Parkinsonian patients with hypersalivation

Ondersteuning

Primaire sponsor: M.E.L. Arbouw,

Hospital Medisch Spectrum TwenteDepartment of clinical pharmacy

P.O. Box 50.000

7500 KA Enschede

The Netherlands

Overige ondersteuning: No funding obtained.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of patients with a decrease of 3 points on the hypersalivation score (on a scale from 1-9).

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

Hospital Medisch Spectrum Twente,
Department of neurology

P.O. Box 50.000
P.J.E. Poels
Enschede 7500 KA
The Netherlands
+31 53 4872000

Wetenschappelijk

Hospital Medisch Spectrum Twente,
Department of neurology
P.O. Box 50.000
P.J.E. Poels
Enschede 7500 KA
The Netherlands
+31 53 4872000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 potassiumchloride tablets, oral digoxin or oral corticosteroids;
11. Kidney function disorders;
12. Pregnancy or lactation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2007
Aantal proefpersonen:	24
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	24-01-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL848
NTR-old	NTR862
Ander register	: APOMST001
ISRCTN	ISRCTN28592111

Resultaten

Samenvatting resultaten

N/A