Pharmacokinetics and -dynamics of needlefree apomorphine administration vs. subcutaneous injections with apomorphine in patients with Parkinson*s disease; a pilot study with a new device

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Primary Objective: To compare the pharmacokinetics of the needlefree system with the Apo-go penject. Secondary objectives: - To assess the clinical effect of Apo-go vs. de needlefree system, using an "automated tap score" and a "Timed...

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

Summary

ID

NL-OMON35723

Source
ToetsingOnline

Brief title
Pharmacokinetics and -dynamics of needlefree apomorphine

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Care4Pharma, Amsterdam,Een eenmalige grant van de producent van het naaldloze systeem (Care4 Pharma) van 7.500 Euro om de plasmasamples te kunnen laten bepalen door Dr. C Movig;apotheker van het MST in Twente;die een apomorfine assay heeft om dit te kunnen bepalen

Intervention

Keyword: apomorphine, injection, needlefree, Parkinson's disease

Outcome measures

Primary outcome

Pharmacokinetic parameters of apomorphine (measured at t=0,

3,6,9,12,15,20,30,45,60,90 minutes) - Absorption/elimination halflifes, AUC,

Cmax and Tmax. - Concentration-effect relationship of the NAS vs. Apo-go

Secondary outcome

Timed Up and Go test AE questionnaire Qualitative Erythema Scale Minolta

erythema assessment 5-point Satisfaction Scale

Study description

Background summary

Apomorphine (Apo-go) pen-ject therapy is a well established, effective and safe rescue therapy for off-periods in Parkinson*s disease (PD). However, one disadvantage of this therapy is the subcutaneous injection of apomorphine, which creates a psychological barrier for some patients to use this rescue opportunity and the injections can cause subcutaneous irritation. Another problem for some patients is injecting themselves during an off-phase, which may create practical hurdles due to for instance rigidity and/or tremor. Recently a new needlefree injection technique was introduced, which may benefit PD patients having problems or subcutaneous irritation with the use of the currently available pen-ject system (Apo-go). To test if the new needlefree

system delivers apomorphine as good as the current Apo-Go system in PD patients, with possibly less skin irritation, a bioequivalence study was designed. Hypothesis: Needleless apomorphine delivery is as effective as the current Apo-go system in patients with Parkinson*s disease, is easier to use and gives less skin irritation in Parkinson's patients.

Study objective

Primary Objective: To compare the pharmacokinetics of the needlefree system with the Apo-go penject. Secondary objectives: - To assess the clinical effect of Apo-go vs. de needlefree system, using an "automated tap score" and a "Timed Up and Go test" - To assess the safety profile of Apo-go and the needlefree system, focusing especially on the skin redness and irritation - To assess the patient satisfaction with the new needlefree system.

Study design

It concerns an intervention study in which the needlefree injection system will be compared with the Apo-go penject system. 1. Patients will be screened at the department of Neurology. 2. Admission to the hospital for 2 days. 3. Patients will not use anti-Parkinson medication from midnight until the first study injection the next day, when they will be in an off-period. Patients will inject the apomorphine themselves, unless they are inable to do so. In that case the researcher will inject the patient for them (this will be taken into account when analyzing patient satisfaction). 4. Sampling of apomorphine plasma concentrations via an intravenous catheter, according to a fixed time schedule (t=0,3,6,9,12,15,20,30,45,60,90,120 minutes) after apomorphine administration. Patients will be randomized for the method of administration received at day one and two. 5. Clinical effectiveness will be assessed by means of the automated tapscore (directly after sampling) and by means of the "Timed Up and Go test" at (t=0,10,20,30,45,60,90,120 minutes). 6. Assessment of AE questionnaires at baseline and after the final sampling time. 7. Assessment of qualitative Erythema Scale and Minolta erythema assessment at baseline and after the final sampling time. 8. Questionnaire regarding patient satisfaction will be filled out after the final blood sampling has taken place. 9. Pharmacokinetic data will be analyzed at the Medisch Spectrum Twente in Enschede, at the lab of the hospital pharmacy (dr. Chris Movig).

Intervention

The intervention is the administration of apomorphine via the needlefree system. The Apo-go penject administration serves as a comparator, as this is the standard method of administration of apomorphine during off-phases in Parkinson*s patients.

Study burden and risks

A two-day admission to the hospital is required. Patients may experience the well-known AE*s of apomorphine, especially nausea, hypotension and subcutaneous inflammation. However, all included patients will be monitored for these AE*s very carefully and continuously during their admission. Furthermore the placement of intravenous catheters may cause local irritation, bleeding and/or infection.

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

Diagnosed Parkinson's Disease according to UK brain bank criteria;Current usage of Apo-go injector;Not satisfied with the current injection pen

Exclusion criteria

Participation in other trials;Dependent on dopaminergic medication at night;Severe cognitive pathology, making it difficult to understand the study procedures

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-11-2011
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	APO-go
Generic name:	apomorphine hydrochloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	14-11-2011
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2011-005241-12-NL
CCMO	NL37621.042.11