A pilot study on the effect of apomorphine on visual perception in patients with Parkinson's disease and visual hallucinations

Published: 24-11-2008
Last updated: 10-05-2024

To gain insight in the cognitive basis of the positive effect of apomorphine on visual hallucinations in Parkinson's disease (PD)

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

Summary

ID

NL-OMON31583

Source
ToetsingOnline

Brief title
Apomorphine and visual hallucinations in Parkinson's disease

Condition

- Movement disorders (incl parkinsonism)

Synonym
hypokinetic rigid syndrome, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Apomorphine, Parkinson, Visual function, Visual Hallucination

Outcome measures

Primary outcome

The change in prestation on the VOSP related to the presence or absence of the apomorphine infusion.

Secondary outcome

1. Lower order visual perception tests consisting of Mars Letter Contrast Sensitivity Test, Visual field measurement, Primary vision measurement, Color differentiation, Visual overview and perceptual speed (TAVTMB).

2. Cognitive and attentional tests consisting of reactiontime (Schuhfried S7), Frontal Lobe assessment Battery (FAB) and the SCOPA-Cog

3. Motor function test consisting of the SPES/ SCOPA.

Study description

Background summary

Visual hallucinations in parkinson's disease are often seen as overstimulation of the dopamine receptors, induced by medication. Dopamine agonist, like apomorphine, are therefore seen as not suitable for the treatment of patients with parkinson's disease and visual hallucinations. In a recent studie apomorphine appeared to have a positive effect on the hallucinations in these patients. In this study the visual and cognitive basis of this change will be studied.

Study objective

To gain insight in the cognitive basis of the positive effect of apomorphine on visual hallucinations in Parkinson's disease (PD)

Study design

This is a pilot study with 10 patients only, to test the hypothesis that the reported positive effects of apomorphine on VH in PD patients are caused by pathological visual processing in these patients.

Methodology
Selection of 10 patients with PD and visual hallucinations (VH)
Baseline scores of visual perception, cognition and attention
Repeated scores after 4 months (based on a known re-test effect within 4 months), initially during an infusion of apomorphine during 3 hours (40ug/kg/hr) and for the second time 3 hrs. after having stopped this infusion.

Intervention

The application of apomorphine via a subcutaneous infusion during three hours.

Study burden and risks

The participants are tested neuropsychologically on two occasions. The first time is a baseline measurement without apomorphine. The second time is four months later when the patients stays in the hospital during one day. On that day there are two test sessions; one while there is as infusion of apomophine and a second test when the apomorphine effect has gone. The risks for the paticipants are therefore very small. Apomorphine is a drug which is regularly used in the treatment of patients with Parkinson's disease. Moreover, any negative effects that may occur are of a short duration because of the short half-life of apomorphine.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9713GZ Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9713GZ Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Diagnosed Parkinson*s Disease according to the UK Brain Bank Criteria
2. Al least weekly hallucinations during the past month
3. MMSE >24
4. FAB>=12
5. Patient must be able to understand the procedure
6. Medication must be stable for at least a month

Exclusion criteria

1. Visual problems (cataract, macula degeneration, severe retinal patholgy, visus<.5)
2. Patients with cerebral electrodes for deep brain stimulation
3. Presence of other neurological or psychiatric affections
4. Unstable internal disease
5. Patients who already use apomorphine

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-07-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

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	EUCTR2007-007936-24-NL
CCMO	NL21163.042.07