The effect of iontophoresis and surfactant on transdermal apomorphine micro-emulsion treatment in patients with Parkinson's Disease

Published: 28-12-2006
Last updated: 09-05-2024

- Is the apomorphine micro-emulsion effective and safe?- Does iontophoresis improve the clinical effect and safety of the micro-emulsion?- Does surfactant improve the effectiveness of the micro-emulsion with iontophoresis without changing the safety…

Ethical review	Approved WMO
Status	Pending
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational invasive

Summary

ID

NL-OMON30219

Source
ToetsingOnline

Brief title
Iontophoretic delivery of apomorphine micro-emulsion with iontophoresis

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, parkinsonism, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Neurologie UMCG

Intervention

Keyword: apomorphine, iontophoresis, Parkinson, transdermal

Outcome measures

Primary outcome

Clinical improvement

- tapping score

- standard scales for clinical improvement

side-effects

-scales

-visual scoringsystem

Secondary outcome

apomorphine plasma concentration

Study description

Background summary

The majority of patients with Parkinson*s disease experience a decrease in the effectiveness of their levodopa treatment after a couple of years. This results in *on-off* fluctuations. Until recently no effective treatment for this phenomenon has been found. Apomorphine has proved to be useful, however, a means for continuous administration is still to be established. At this moment adequate plasma levels can be attained with transdermal administration of an apomorphine micro-emulsion. Iontophoresis could be useful in elevating these levels and could offer potential for an accurate regulation.

Study objective

- Is the apomorphine micro-emulsion effective and safe?

- Does iontophoresis improve the clinical effect and safety of the micro-emulsion?

- Does surfactant improve the effectiveness of the micro-emulsion with iontophoresis without changing the safety

Study design

The patients are asked to spend three separate days in the UMCG. They are consecutively treated with transdermal apomorphine micro-emulsion (AME), AME plus iontophoresis and subsequently with AME iontophoresis and surfactant. For internal control they are also treated with apomorphine intravenously.
The clinical effect will be determined by unilateral tapping scores and standard scales for clinical improvement. Local and general side effects are determined by questionnaires and local dermal side effects by a visual scoring system.

Study burden and risks

Earlier research has pointed out that transdermal apomorphine delivery does not cause any risks. Concerning iontophoresis there is the possibility of some slight local side effects. This includes itching en tingling. Some mild erythema can occur, which will disappear spontaneously. Iontophoresis does not cause pain.
Five ml of blood will be drawn through an infuse approximately twenty times a day. Furthermore the patient will be given a subcutaneous apomorphine injection and has to spend three separate days in the hospital.

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

- Patients with parkinson's disease with at random fluctuations that are insufficiently medicated with oral parkinson medication
-age > 18
-patient signed approved informed consent;-patient should be capable of understanding the protocol

Exclusion criteria

- severe reaction on subcutaneous apomorphine test
-little skin pigmentation combined with burned skin
-instable internal pathology
-changes in parkinson medication during the past month
-Mini Mental State Examination <24
- Orthostatic hypotension

Study design

Design

Study phase:	2
Study type:	Observational invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-11-2006
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Britaject
Generic name:	Apomorphine
Registration:	Yes - NL outside 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	EUCTR2006-005639-11-NL
CCMO	NL14725.042.06