The effect of betahistine 48 mg three times daily on motion sickness

Published: 25-03-2008
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To assess the effect of betahistine on the severity / intensity of motion sickness

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32365

Source
ToetsingOnline

Brief title
betahistine

Condition

- Other condition
- Aural disorders NEC

Synonym
motion disturbance, motion sickness

Health condition

bewegingsziekte

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Bedrijf,Solvay Pharmaceuticals

Intervention

Keyword: betahistine, desdemona, motion sickness

Outcome measures

Primary outcome

It is expected that betahistine will diminish motion sickness. In both conditions of the experiment subjects will be exposed to the same motion stimulus. This stimulus will last for half an hour, or less if a certain motion sickness level (**moderate nausea**), indicated by the subject, is reached prior to the end of the 30 min period. The exposure duration is the main study parameter.

The tests at the screening have a dual goal: to determine the participants*motion sickness susceptibility level, and to determine which motion stimulus is provocative enough to induce motion sickness within 30 minutes, but not within a few minutes. For this test, a motion sickness inducing stimulus will be chosen that does not invoke hyperventilation. To this effect the breathing of the subjects is analysed during the tests so that hyperventilation can be excluded.

Secondary outcome

n.a.

Study description

Background summary

Conventional motion sickness medication has the side effect of sleepiness. For travellers that have to fulfil certain tasks or responsibilities aboard a car,

plane or ship (or other moving entity), such side effects are not desirable. This prompts the need for motion sickness medication that is suitable for professionals such as crew members, pilots or sailors.

This study will evaluate the impact of betahistine on motion sickness. It is anticipated that intake of betahistine will diminish feelings of motion sickness in comparison with placebo.

Study objective

To assess the effect of betahistine on the severity / intensity of motion sickness

Study design

The study is designed as a randomized, cross-over, placebo-controlled, double-blind study. The study will be conducted during a three-week period in which 26 volunteers will be subjected to two conditions. They will visit TNO three times. Once for a screening and twice more for the actual experiment. Before each test session, subjects will have taken placebo or betahistine during one week. The study will be conducted in the test device Desdemona.

Intervention

All subjects will receive the following study treatment: The first week subjects take 48 mg betahistine three times daily (3x48 mg) or a placebo three times daily. The second week they take the opposite of what they took the week before (3x48 mg betahistine or 3xplacebo)

Study burden and risks

Before the study, subjects will be screened, based on their medical history and they will undergo a physical examination to ascertain their health. Also they will be tested in the Desdemona facility to establish their susceptibility for motion sickness
After the intake, the subjects will visit TNO two times. Each time they may reach the moderate nausea level, which in all conditions is also an endpoint. The after-effects of motion sickness are short-lasting.

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Female volunteers should take oral contraceptives (combined or progestogen only). Body Mass Index (BMI) 18-28 kg/m2
Healthy as assessed by health questionnaire (Pbetahistine F02; in Dutch) and a physical examination limited to auscultation of heart and lung, blood pressure and heart rate
Susceptibility to motion sickness is more than 35 on Golding*s MSSQ scale.

Exclusion criteria

Participation in any clinical trial including blood sampling and/or administration of substances up to 30 days before Day 01 of this study
Having a history of medical or surgical events that may significantly affect the study outcome
Clinically relevant medical problems (vestibular, cardiovascular, pulmonary, gastrointestinal, neurological, psychiatric, hepatic, renal, hematological or other organic abnormality or pathology, including: asthma, ulcus pepticum urticaria, or allergic complaints as a rash or allergic rhinitis).
Participation in any non-invasive clinical trial up to 30 days before Day 01 of this study
Subjects who are mentally handicapped.

Subjects who have taken (non)prescription medications within the last 14 days, with the exception of painkillers such as aspirin, paracetamol, ibuprofen, up to 72 hours prior to the start of the study.
Inclination to hyperventilation (Nijmegen questionnaire score > 23)
Not able to undergo the familiarization tests inside the moving base-simulator Desdemona
Alcohol consumption females > 21 or units/week; males >28 units/week
Pregnancy or breastfeeding

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2008
Enrollment:	26
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	betaserc
Generic name:	betahistine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	25-03-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	EUCTR2008-000885-21-NL
CCMO	NL22006.028.08