Effects of morning versus evening dose of hydroxyzine 50 mg on cognition in healthy subjects

Published: 18-05-2009
Last updated: 04-05-2024

Primary: To explore the effect of the H1-antagonist hydroxyzine 50 mg on motor response, attention and impulsivity, using a test battery and task manipulations. Secondary: To explore the effect of the H1-antagonist hydroxyzine 50 mg on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33183

Source
ToetsingOnline

Brief title
Cognition in subjects after morning versus evening of an antihistamine

Condition

- Other condition

Synonym
sedation / drowsiness

Health condition

cognitief functioneren

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Antihistamine, Cognition, Hydroxyzine, Sleep-wake cycle

Outcome measures

Primary outcome

The Mean Absolute Tracking Error (mm) in the Divided Attention Task

Secondary outcome

Cognitieve tests: Attentional Network Test; Critical Tracking Test; Divided

attention Test; Stop Signal Test; Attentional Switch Test; Event related

potentials: P1/N1, N2, P3.

Subjectieve evaluaties: Groningen Sleepiness Questionnaire; Subjective

Alertness Bond en Lader Visual Analogue Scale

Study description

Background summary

One of the most prominent side effects of antihistamines is sedation. Due to this sedation there is a decrease in workproductivity, an increased absenteïsm from work or school, and an increased risk for traffic accident.
Antihistamines are dicided in first and second generation medications. First generation antihistamines cause sedation, whereas second generation antihistamines have been found to be mildly sedative, or even mildly stimulating. It is assumed that this difference in sedation could be explained by their capacity to enter the brain. However, this mechanism alone can not explain the difference between first and second generation antihistamines. Other factors may also determine the presence or absence of sedation, such as the circadian rhythm. It is assumed that although the firing of histaminergic neurons stops during several stages of sleep, the synthesis of histamine might continue.

Because of that, the mechanism responsible for the reversion of sedative effects might be mediated by restoring the balance between histamine release and synthesis after sleep. This would mean that the histamine availability will be greatest shortly after awakening. Because of that, the antihistamine will have less binding potential during that time compared to other times of administration. Therefore, it is hypothesized that the behavioural effect of an antihistamine is apparent in the evening after an evening dose condition, but will be smaller in the morning after a morning dose condition due to the excessive release of histamine shortly after awaking.

Study objective

Primary: To explore the effect of the H1-antagonist hydroxyzine 50 mg on motor response, attention and impulsivity, using a test battery and task manipulations.
Secondary: To explore the effect of the H1-antagonist hydroxyzine 50 mg on electrocortical indicators using event related potentials.

Study design

Double blind, placebo controlled, 3-way crossover design

Intervention

During the study, alle volunteers will experience the following testconditions:
1. Hydroxyzine 50mg and placebo
2. Placebo and Hydroxyzine
3. Placebo and placebo

Study burden and risks

Subjects will visit the study centre and be monitored by one of the investigators for examination during medical screening (45 minutes); for training of cognitive tests and one habituation period (13 hours); and three treatment periods consisting of an evening, night and following morning (15 hours in each treatment period, in total 58.75 hours including 32 hours of sleep). Blood samples are drawn during screening (10ml) and three treatment periods (5ml). During treatment periods subjects perform cognitive tests and ERPs are measured. The investigational product hydroxyzine is a first generation antihistamine. Its principal indications are: treatment of allergic pruritis, nausea and anxiety. Administration of hydroxyzine is possible to cause side-effects, as mentioned in chapter 6. However, the reported effects generally disappear within 24 hours after administration. This study is relevant in order to get better insights about the mechanism of H1-antagonists. With more insights in these mechanisms, the administration of antihistamines

can be adjusted in order to be more effective and less sedative.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 40
6229 ER Maastricht
Nederland
Scientific
Universiteit Maastricht

Universiteitssingel 40
6229 ER Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Healthy
2. Between 18 and 45 years of age
3. BMI between 19 and 30
4. Able to give a written informed consent and to understand the protocol

Exclusion criteria

1. Pregnancy
2. Use of antihistamine
3. Excessive alcohol, nicotine and/or caffeine consumption
4. Psychiatric illness

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2009
Enrollment:	22
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ATARAX
Generic name:	Hydroxyzine dihydrochloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	18-05-2009
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2009-012340-16-NL
CCMO	NL27642.068.09