The effects of morning versus evening dose of an antihistamine on cognition.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26397

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Sedation / sedatie
Antihistamines / antihistaminica

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Maastricht University

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Sensori-motor test: Critical Tracking task;

2. Attention task: Attentional Network Test;

3. Impulsivity tests: Stop Signal Task, Attentional Switch test;

4. Event related potentials: P1, P3, N1, N2.

Study description

Background summary

The mechanism responsible for the reversion of sedative effects caused by antihistamines might be mediated by restoring the balance between histamine release and synthesis after sleep. This would mean that histamine availability will be greatest shrotly after awakening. Because of that, the antihistamine will have less binding potential during that time compared to other times of administration. This study focuses therefore on the time-depending effects of the antihistamine hydroxyzine on cognition.

Study objective

The behavioural effects of an antihistamine is apparent in the evening after an evening dose, but will be smaller in the morning after a morning dose condition due to the excessive release of histamine shortly after awaking.

Study design

Three testperiods of each an evening, a night and the morning after.

Intervention

1. Hydroxyzine 50 mg;

2. Placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Aged between 18 and 45 years;

2. Healthy volunteers;

3. BMI between 19 and 30;

4. Able to give a written informed consent;

5. Able to understand the protocol and to come to the visits;

6. Use of a contraceptive method (for women).

Exclusion criteria

1. Medical history of major medical, psychiatric illness or surgery which, in the judgement of the investigator, could jeopardize their health or is likely to modify their handling of the study drug;

2. Any non corrected visual defect or locomotor disorder which could interfere with the study;

3. Acute or chronic systemic disease or disorder;

4. History of hypersensitivity to H1 antihistamines, benzimidazoles or lactose;

5. Seasonal allergic rhinitis or urticaria treated by antihistamine;

6. History of alcohol or drug abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2009
Enrollment:	18
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1706
NTR-old	NTR1816
Other	MEC MUMC : 09-3-025
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A