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

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26397

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Sedation / sedatie
Antihistamines / antihistaminica

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Maastricht University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

1. Hydroxyzine 50 mg;

2. Placebo.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	04-06-2009
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1706
NTR-old	NTR1816
Ander register	MEC MUMC : 09-3-025
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A