The effects of the antihistamine bilastine on actual driving performance.

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The main of the study is to gain more information about the sedative effects of two doses (20 and 40 mg) of bilastine and to assess the effect of repeated dosing on the road driving ability. It is expected that no differences will be detected...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27203

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

allergic rhinitis
Sedation
antihistamine
Bilastine

Ondersteuning

Primaire sponsor: FAES FARMA S.A.
Overige ondersteuning: FAES FARMA S.A.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Standard deviation of the lateral position (SDLP) in the Road Tracking test on day 1 and 8.

Toelichting onderzoek

Achtergrond van het onderzoek

Bilastine is a newly developed antihistamine. The main of the study is to gain more information about the sedative effects of two doses (20 and 40 mg) of bilastine and to assess the effect of repeated dosing on the road driving ability. It is expected that no differences will be detected between bilastine and placebo, and that differences will be detected between bilastine and placebo vs hydroxyzine using the actual driving test.

Doel van het onderzoek

The main of the study is to gain more information about the sedative effects of two doses (20 and 40 mg) of bilastine and to assess the effect of repeated dosing on the road driving ability. It is expected that no differences will be detected between bilastine and placebo, and that differences will be detected between bilastine and placebo vs hydroxyzine.

Onderzoeksopzet

Day one and day 8 of each of four periods are testdays.

Onderzoeksproduct en/of interventie

1. Bilastine 20 mg;

2. Bilastine 40 mg;

3. Placebo;

4. Active control: hydroxyzine.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Aged between 21 and 45 years;

2. Healthy volunteers;

3. BMI between 19 and 30;

4. Having a valid driving licence for more than 3 years;

5. Having a driving experience of at least 5000 km per year;

6. Able to give a written informed consent;

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

8. 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 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:	04-06-2008
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-03-2009
Soort:	Eerste indiening

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	NL1635
NTR-old	NTR1732
Ander register	: Bila 2707/UMA
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A