The effects of the antihistamine bilastine on actual driving performance.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27203

Source
Nationaal Trial Register

Brief title
N/A

Health condition

allergic rhinitis
Sedation
antihistamine
Bilastine

Sponsors and support

Primary sponsor: FAES FARMA S.A.
Source(s) of monetary or material Support: FAES FARMA S.A.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Standard deviation of Speed (SDSP) in the Road tracking test on day 1 and 8;

2. Safety parameters: clinical signs and symptoms from physical examination, adverse evetns, laboratory safety, vital signs and ECGs.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

1. Bilastine 20 mg;

2. Bilastine 40 mg;

3. Placebo;

4. Active control: hydroxyzine.

Contacts

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Eligibility criteria

Inclusion criteria

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).

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 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):	04-06-2008
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-03-2009
Application type:	First submission

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

Study results

Summary results
N/A