Effects of Single Dose of Bilastine 20mg on Flying Ability in Healthy Volunteers Under Conditions of Simulated Cabin Pressure

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Objective: The response over time on daytime alertness and performance will be assessed following a single oral dose of bilastine 20 mg in healthy volunteers performing flying ability tests in a hypobaric chamber with an ambient pressure of 75.2 kPa...

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

Summary

ID

NL-OMON41124

Source
ToetsingOnline

Brief title
BISCAT

Condition

- Allergic conditions

Synonym
allergic rhinoconjunctivitis, allergies, hives, urticaria

Research involving
Human

Sponsors and support

Primary sponsor: TNO

Source(s) of monetary or material Support: FAES FARMA S.A.,FAES Farma SA

Intervention

Keyword: alertness, Bilastine, cabin pressure, flying ability

Outcome measures

Primary outcome

Main study parameters/endpoints:1) Vigilance &Tracking Test (VigTrack): root mean square of tracking error, percentage omissions, number of false reactions; 2) Multi-Attribute Task Battery (MAT): a) Monitoring performance: number of false reactions, number of omissions, mean response time; b) Tracking performance: root mean square of tracking error; c) Resource management: mean absolute deviation from target; 3) Stanford Sleepiness Scale (SSS): SSS-scores.

Secondary outcome

n/a

Study description

Background summary

Rationale: Optimal physical and mental fitness of the pilots is a prerequisite for flight safety. Pilots suffering from allergic rhinoconjuctivitis or other allergic diseases are not allowed to fly because ambient pressure changes may aggravate the symptoms and some antihistaminic medication may interfere with flight safety, probably due to their sedative effects. Bilastine is a new second-generation highly selective H1 antihistamine that has been developed for the treatment of allergic rhinoconjunctivitis and urticaria. Bilastine is considered to have no sedative side effects and no cardiotoxic effects and may, therefore, provide a safe therapeutic alternative to keep pilots suffering from allergic rhinitis on flying status. A single oral dose of bilastine 20 mg had minimal brain H1 receptor occupancy, was not associated with subjective sedation or objective impairment of psychomotor performance and driving ability, and was devoid of treatment-related sedative adverse effects, thus satisfying relevant subjective, objective criteria as a non-sedating

antihistamine. Although 20 mg bilastine produced no significant impairment of cognitive and psychomotor performance, it should be excluded that the drug may affect flying abilities of pilots working in an airliner cabin environment with lowered ambient pressure.

Study objective

Objective: The response over time on daytime alertness and performance will be assessed following a single oral dose of bilastine 20 mg in healthy volunteers performing flying ability tests in a hypobaric chamber with an ambient pressure of 75.2 kPa, which equals an airliner cabin altitude of about 8,000 feet.

Study design

Study design: This will be a single-center, randomized, double-blind, placebo-controlled, crossover study using single doses of bilastine 20 mg, placebo, and hydroxyzine 50 mg as an active control.

Intervention

Intervention: In a crossover design all subjects will receive bilastine 20 mg, hydroxyzine 50 mg, and placebo on three respective treatment days. There will be at least a seven-day washout between each treatment day.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Volunteers have to visit the institute for screening, training on the tasks, and familiarization in the hypobaric chamber (total 0.5 day) and have to undergo the assessments on 3 separate trial days. Each trail day lasts 8 hours of which 7 hours are spent in the hypobaric chamber with an ambient pressure equalling the cabin pressure of an airliner. Under these circumstances peripheral oxygen saturation may decrease by 5-10%, which is known to be easily tolerable without health complaints. Reported adverse effects of bilastine are headache, somnolence, dizziness, and abdominal pain (all infrequent, mild and with an incidence not different from placebo). Reported adverse effects of the active control hydroxyzine are dry mouth, drowsiness, sleepiness, dizziness, hypotension, headache, allergic reactions, pruritus, rash, urticaria, and hallucinations. It is anticipated that all reported adverse effects recover spontaneously after termination of the treatment. It is considered that the possible adverse effects of the study medication and/or hypobaric conditions are non-health threatening and acceptable. The outcome of the study may provide a safe therapeutic alternative for pilots suffering from allergic rhinitis, or urticaria.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- All subjects must be normal healthy (non-smoking) males ages 18-40 of any race.;- Negative urine screen for drugs with a high potential for abuse.;- Subjects must be free of any clinically significant disease which would interfere with the study evaluations or study treatments.;- Subjects must have an ECG -QTc time within normal limits ;- Body Mass Index must be between 19 and 30 kg/m2;- Subjects must be willing to give written informed consent and must be able to adhere to dosing and visit schedules and meet study requirements.;- Adequate adaptation towards the differences in cabin pressure

Exclusion criteria

- Subjects who have clinically significant abnormal physical findings or vital signs which could

interfere with the objectives of the study. This includes subjects who have any history or symptoms of chronic illness, history of psychotic disorders, drug addiction or abuse of drugs or alcohol, or impaired mentation which could interfere with the completion of the study.;- Subjects requiring any CNS medication, or medication with sedative effects. ;- Subjects who have taken macrolide Antibiotics, antifungals, cimetidine, ranitidine within 7 days before the study;- Use of (non) prescription medications within the last 14 days, with the exception of aspirin and paracetamol up to 48 hours prior to the start of the study;- alcohol consumption of more than 21 units per week; ca*eine consumption of more than 6 cups per day; regular drinking of citric or grapefruit juice; treatment by atropine or atropine-like drugs;- Subjects with a history of allergies to more than two classes of medication or who are allergic to or cannot tolerate antihistamines.;- Subjects who have had an upper respiratory tract or sinus infection or who have had a viral upper respiratory infection within 7 days prior to Screening.;- Subjects with active seasonal and/or perennial allergic rhinitis.;- Subjects with urticaria;- The investigational study staff involved with this study.;- Subjects who have taken a sedative/hypnotic, antihistaminic or anticholinergic drugs during the three weeks prior to entering the first treatment phase.;- Subjects who have consumed alcoholic beverages within the last 24 hours prior to the start of the study or during the treatment study days.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2014
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Atarax
Generic name:	hydroxzine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Bilaxten
Generic name:	Bilastine

Ethics review

Approved WMO Date:	23-10-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-11-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	EUCTR2014-003299-22-NL

Register	ID
CCMO	NL50566.028.14