STUDY TO INVESTIGATE THE EFFECTS OF LEVOCETIRIZINE AND HYDROXYZINE ON COGNITIVE AND PSYCHOMOTOR FUNCTIONING DURING SIMULATED DIVING AT 2 BAR AND 4 BAR IN PROFESSIONAL NAVY DIVERS

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Investigate the effects of levocetirizine, hydroxyzine and placebo on cognitive and psychomotor functioning during controlled simulated diving in a hyperbaric chamber in professional navy divers at 10 mt (2 bar) and 30 mt (4 bar).

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

Summary

ID

NL-OMON34370

Source
ToetsingOnline

Brief title
Levocetirizine and Diving

Condition

- Other condition

Synonym
Allergic rhinitis

Health condition

Allergische rhinitis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognitive, Diving, Levocetirizine, Psychomotor

Outcome measures

Primary outcome

The percentage of errors on the tests.

Secondary outcome

Reaction time.

Study description

Background summary

Antihistamines are commonly used and currently levocetirizine is most frequently prescribed in the Netherlands. They are commonly used by divers, to solve ear, nose and throat problems, especially to open tubal passage. All antihistamines cross the blood-brain barrier, where they block the H1-receptors. First-generation antihistaminic drugs (like hydroxyzine) are associated with sedation, CNS-depressant effects and an impairment of cognitive and psychomotor functions. They bind non-selective to the H1-receptors in the brain and interact with adrenergic, serotonergic and cholinergic neurons. This causes sedative effects. Second-generation antihistamines have less lipophilic properties than the first generation and bind more selective to the H1-receptors. Third-generation antihistamines are supposed to have no unwanted sedative effects.
While diving, increased pressure and different N2/O2 concentrations are known to affect performance at a depth of 20 mt (3 bar) or deeper. This is caused by nitrogen narcosis. Nitrogen narcosis is caused by competitive binding of nitrogen to synapses of nerve ends in the body. This causes that

neurotransmitters cannot bind, which causes disturbance of the nerve system. As a result, effects such as impaired neuromuscular coordination, slowed mental activity, euphoric feelings and impaired memory, have influence on the psychomotor and cognitive functions have been reported. Adverse effects of psychoactive drugs can be additive or interact with the effects of diving. Unfortunately, scientific research in this area is scarce. Therefore, physicians are careful when prescribing medication to divers. The unknown effects during increased pressure, different N2/O2 concentration, the uptake and elimination of inert gas, and the risk that medication can act synergistic on the sedative effects of nitrogen narcosis often make physicians to choose (a) not to prescribe psychoactive medication, or (b) prohibit diving while treated.
This study investigates the effects of antihistamines in hyperbaric conditions.

Study objective

Investigate the effects of levocetirizine, hydroxyzine and placebo on cognitive and psychomotor functioning during controlled simulated diving in a hyperbaric chamber in professional navy divers at 10 mt (2 bar) and 30 mt (4 bar).

Study design

A double-blind, placebo-controlled crossover study.

Intervention

Each subject performs 3 test days: levocetirizine (5 mg), hydroxyzine (50 mg) and placebo.

Study burden and risks

The dive profile/procedure has the approval of the Surgeon General and the Super Intendant of Diving of the Royal Netherlands Navy. The dive test is within the normal safety limits and is not an exceptional exposure according the RNLN Diving Manual. The dive profile fits within the regular training capabilities of the participants.
The risks are minimal, because tests are performed in a diving simulator supervised by medical and technical personnel. Subjects are professional Navy divers. Dives are not known to produce serious adverse events. Adverse events usually disappear within a couple of hours after intake of the drugs. There are no specific benefits for participants, besides gaining insight in their own diving performance. Military divers will receive reimbursements for the diving according Navy regulations based on depth/time profile. They will recieve 120 euro for each simulated dive, 360 euro for the complete study.

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

Man
He is aged between 18 and 55 years old
BMI between 18 and 30
Written informed consent
Normal static binocular acuity, corrected or uncorrected
Normal hearing
Possession of a valid divers certificate and medical fit for diving
Be considered as reliable and mentally capable of adhering to the protocol.

Exclusion criteria

Female
Current drug use (questionnaire at the start of the test day)
Use of psychoactive medication
Prior enrolment in the same study
Physical or mental illness
Excessive alcohol use (>21 alcoholic drinks per week)
Intake of caffeine-containing beverages over 5 glasses per day
Smoker

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):	23-04-2012
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Atarax
Generic name:	Hydroxyzine
Registration:	Yes - NL outside intended use

Product type:	Medicine
Brand name:	Xyzal
Generic name:	Levocetirizine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-10-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2010-021153-40-NL
CCMO	NL32781.041.10