

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

Published: 09-04-2010

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

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35024

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

Reaction time.

Secondary outcome

The percentage of errors on the tests.

Study description

Background summary

Divers may use psychoactive medication. The effects of these drugs on cognitive performance have not been investigated during diving.

Study objective

Investigate the effects of levocetirizine, diphenhydramine and placebo on cognitive and psychomotor functioning during controlled simulated diving in a recompression 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

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Each subject performs 3 test days: levocetirizine (5 mg), diphenhydramine (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.

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

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:	Other

Recruitment

NL
Recruitment status: Will not start
Start date (anticipated): 01-04-2010
Enrollment: 25
Type: Anticipated

Medical products/devices used

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

Ethics review

Not approved
Date: 07-04-2010
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	EUCTR2010-019147-19-NL
CCMO	NL31760.041.10