

Validation of adapted DCIEM Heliox diving tables using nitrox decompression

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The proposed research intends to gather data to validate the hypothesis that using Nitrox to decompress during Heliox diving will significantly decrease the time and equipment requirements for decompression while being as safe as the standard heliox...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON47192

Source

ToetsingOnline

Brief title

validation of adapted DCIEM heliox tables

Condition

- Other condition

Synonym

decompression illness, decompression sickness

Health condition

hyperbare aandoeningen met name voorkoming decompressieziekten

Research involving

Human

Sponsors and support

Primary sponsor: Koninklijke Marine

Source(s) of monetary or material Support: Interspiro AB, Ministerie van Defensie; kosten METC toetsing wordt betaald door Industrie

Intervention

Keyword: heliox diving, nitrox, tables, validation

Outcome measures

Primary outcome

Changes in bubble scores as described by Kisman-Masurel (K-M) after the dive at specified time points.

Secondary outcome

not applicable

Study description

Background summary

For deep diving operations, Netherlands Navy divers use a breathing medium called Heliox, which can be breathed at a constant fraction of 16% oxygen and 84% helium. During decompression on Heliox there is a requirement to decompress on both air and oxygen. This type of diving is only done with Surface Supplied Diving systems where an umbilical (gas hose) delivers the breathing medium to the diver. The first stops during the decompression phase are conducted with air and once the diver reaches 9 metres of sea water (msw), 100% oxygen is used. This process therefore requires switching from the initial Heliox gas to air and then to oxygen to complete the decompression requirement. Using nitrox (60% oxygen and 40% nitrogen) as a decompression breathing gas could result in a saving of about 10% to 15% in overall decompression times compared with the standard heliox tables nowadays used. Furthermore only one switch in breathing gas is necessary. A feasibility study performed by DRDC seems to underline this hypothesis.

Study objective

The proposed research intends to gather data to validate the hypothesis that

using Nitrox to decompress during Heliox diving will significantly decrease the time and equipment requirements for decompression while being as safe as the standard heliox tables nowadays used.

Study design

Observational study

Study burden and risks

Burden: all divers have to make 3-6 dives. Before the dive they have to fill in a pre-dive questionnaire. During the dive they have to frequently score thermal comfort. After each dive they undergo Doppler measurements for at least 3 times.

Benefits: For military diving, it is of importance to use safe diving tables. Furthermore, diving tables with shorter decompression time could be operational beneficial. However these shorter decompression times should not lead to a higher incidence of decompression sickness (DCS).

Risks assessment, group relatedness: The risk of DCS associated with this dive simulation can be considered as very small ($< 1.0\%$). When a diver encounters symptoms of DCS he will be treated according to the guidelines used within the Royal Netherlands Navy, which are equal to those internationally used. Beside the risk of decompression sickness, there is the risk for central nervous system oxygen toxicity, which is estimated as $< 0.01\%$. Furthermore, as described in the information package subjects participating in this trial run a small risk on hypothermia, hypercapnia, and hypoxia. All in all, we think the risk of these simulations can be considered low, and equal to a real, wet operational heliox dive.

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

adult males, professional divers, medically fit to dive

Exclusion criteria

if one of the inclusion criteria is not met, recent infection and/or flue, any previous decompression sickness, daily use of alcoholic beverage

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 17-02-2015

Enrollment: 50

Type: Actual

Ethics review

Approved WMO	
Date:	26-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	04-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL48626.018.14

Study results

Date completed:	12-10-2018
Actual enrolment:	53