Hyperbaric oxygen and pulmonary toxicity

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22684

Source
NTR

Health condition

ENG: pulmonary oxygen toxicity, oxygen diving, oxygen poisoning.

DUTCH: pulmonale zuurstof toxiciteit, zuurstof duiken, zuurstofvergiftiging.

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Amsterdam
P.O. Box 22660
1100 DD Amsterdam, the Netherlands
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Source(s) of monetary or material Support: Royal Netherlands Navy

Intervention

Outcome measures

Primary outcome

Changes in EB, DLNO/CO compared to baseline after air and oxygen dives.

Secondary outcome

a. Difference in EB measured by SpinoNose or GCMS.

b. Time interval post-dive which gives the best markers for POT.

Study description

Background summary

Breathing oxygen at a partial pressure (PO2) of more than 50 kPa for a longer duration can lead to pulmonary oxygen toxicity (POT). (Klein 1990, Miller 1981) The most mentioned changes which can be found are atelectasis, interstitial oedema and inflammation. (Sackner 1975) These changes are reversible. (Winter 1972) However, when the administration of oxygen is continued, this will eventually lead to irreversible lung fibrosis. (van Ooij 2013, Kapanci 1972)

The current standard for determining POT in diving and hyperbaric medicine, is a decrease in vital capacity (VC). (Clark 1970) Bardin & Lambertsen related the decrease in VC to the PO2 and time exposed to oxygen and introduced the unit of pulmonary toxicity dose (UPTD). (Bardin 1970) To cope with the wide range of inter- and intrapersonal variability, the limits of acceptable oxygen exposure are based on median decreases in VC. For instance; 450 UPTD gives a 2% decrease in VC in 50% of the cases. The decrease in VC was derived from dry-dives (in a recompression chamber), not from actual hyperbaric oxygen in an immersed setting. At the time of publication, the authors recognized the limitations of the model and suggested that more advanced research techniques would probably increase the validity of the UPTD model.

Recent publications indicate that more advanced parameters such as diffusion capacity of carbon monoxide (DLCO) and nitric oxide (DLNO), could more accurately determine POT. (van Ooij 2014) However, these measurements are quite difficult to perform and require specialised equipment. Therefore, these methods cannot be used by clinicians or divers as a measurement of POT in an outward setting. In combination with the recent findings that immersion affects the rate at which POT develops and the high intra- and interpersonal variance, the diving industry and the field of hyperbaric medicine needs a new and valid model which allows correction for individual susceptibility.

In an earlier study we found volatile organic compounds (VOCs) detected in a single exhaled

breath (EB) four hours after a hyperbaric exposure (with Gas Chromatography Mass Spectrometry [GCMS] analysis). (van Ooij 2014) The conclusion if this study was that more accurate EB measurement should be performed less than four hours post-dive, however the exact moment is unknown. Also, the GCMS-analysis requires an external laboratory. Therefore, the traditional method analysing EB does not meet the requirements of point-of-care testing.

With the recent development of the SpiroNose® by the department of respiratory medicine in the Academic Medical Center a highly advanced technique became available to overcome these difficulties. The SpiroNose allows analysis of EB and compare it to an online database. However, no research has been conducted to validate VOCs detected by the SpiroNose are just as valid as GCMS to detect POT after (immersed) hyperbaric oxygen exposure.

Our hypothesis is that VOCs detected with the SpiroNose in a single exhaled breath are just as valid as DLNO/CO and are a patient-friendly and easy to use method to detect POT after hyperbaric oxygen exposure.

Study objective

a) Analysis of exhaled breath is able to distinguish between oxygen and compressed air.

b) The SpiroNose (R) is a valid instrument for analysis of exhaled breath compared to Gas Chromatography Mass Spectrometry (GC-MS).

Study design

immersed dives: sampling of exhaled breath: once pre dive, post dive at 30 minutes, 1 hour, 2 hours, 3 hours and 4 hours.

dry dives: sampling of exhaled breath: once pre dive and post dive at 30 minutes, 2 hours and 4 hours.

Intervention

a) Submersed exposure (diving) wit a PO2 of 190 kPa or PO2 40 kPa for 60 minutes.

b) Series of dry exposures (recompression chamber) with a PO2 250 kPa for 90 minutes in 5 days plus once after 2 days of rest.

Contacts

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Eligibility criteria

Inclusion criteria

- Adult males or females

- Non-smoking

- Fit to dive according to the European Diving Technology Committee (EDTC) standards. (includes lung function tests such as DLCO % reference ERS/ATS > 70%)

- Certified Navy (Special Forces) Divers (only applicable to wet-dives)

- Certified hyperbaric Navy personnel (only applicable to dry-dives)

Exclusion criteria

- If one of the inclusion criteria is not met

- Recent lower respiratory tract infection and/or flue

- Daily use of alcoholic beverages

- Use of (over the counter) medication

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	25
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44355
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6363
NTR-old	NTR6547
CCMO	NL61779.018.17
OMON	NL-OMON44355

Study results

Summary results
N/A