Hyperbaric oxygen and pulmonary toxicity

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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).

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22684

Bron
Nationaal Trial Register

Aandoening

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

DUTCH: pulmonale zuurstof toxiciteit, zuurstof duiken, zuurstofvergiftiging.

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Amsterdam
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Overige ondersteuning: Royal Netherlands Navy

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44355
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A