Influence of body fat and plasma lipid compounds on venous gas embolism resulting from a dry air-dive simulation

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Main objectives: Establishing the effect of BF as predisposing factor for the development of VGE and hence DCS by using subjects with a restricted range in age and VO2max. Establishing the effect of TC/HDL ratio and FFA as predisposing factors for...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON34634

Source
ToetsingOnline

Brief title
Influence of bodyfat and lipids on venous gas embolism of divers

Condition

- Other condition

Synonym
decompression sickness, divers' disease

Health condition

decompressieziekte

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Hytech BV en Smit Salvage, ieder voor 1000 Euro.,SUBSIDIES van instanties en bedrijven uit de (beroeps)duikwereld. het gaat om kleine bedragen.

Intervention

Keyword: bodyfat, divers, lipids, venous gas embolism

Outcome measures

Primary outcome

Main study parameter/endpoint

Dependent variable (outcome): VGE score (Kismann-Masurel Doppler score).

Independent variables: BF%, TC/HDL ratio, FFA-level.

Secondary outcome

7.1.2 Other study parameters (if applicable)

Albumine. Confounders: age and VO2max (both restricted in range)

Study description

Background summary

For decades, it is well known that decompression sickness (DCS) in divers, caisson workers and aeronautic personnel is caused by intravascular and/or extra-vascular bubbles of inert gas. In many cases of DCS vascular bubbles, especially venous bubbles are the cause; venous gas embolism (VGE). For many years, one of the intriguing questions was why the one diver is much more vulnerable to obtain VGE then the other. When breathing air, the gas forming bubbles is nitrogen. For decennia, dive research tries to elucidate which physiological parameters determine VGE. Susceptibility to VGE varies enormous among divers with seemingly similar physical characteristics.
It has been well established that VGE susceptibility increases with age and decreases with VO2max. The influence of BF as an independent determent is controversial. One of the reasons of the fact that the influence of fat% is still unknown is that fat% is highly correlated with age and negatively

correlated with VO2max.
BF as predisposing factor
The body fat compartment can enhance VGE, since after ascent a substantial part of the total body dissolved nitrogen is accumulated in BF, and the more the higher BF%. Since in the blood bubbles and the liquid phase compete for the N2 release in the blood, BF may directly influence VGE vulnerability. To study fat% as an independent predisposing factor, we restrict the influence of the factors age and VO2max by limiting their range..
Surfactants as predisposing factors
VGE bubbles arise from small nuclei (about 0.1 *m and smaller). However, such small nuclei will collapse soon after their genesis due to their very large surface tension that is larger the smaller the nucleus or bubble. A nucleus can only survive when it is stabilized by a monomolecular layer of surfactant molecules counteracting the inward force of the surface tension. These molecules should have an amphiphilic nature: a hydrophilic group pointing outward and a hydrophobic tail pointing inward. FFAs are theonly candiates (3D-structure, concentration, physical intermolecular forces, thermodynamics). FFA is weakly ionogenic bound to albumin and should be released (thermodynamics) to frorm mycelles. The more FFAs, the easier bubbles are stabiilized. Due to the (chemo-)physical characteristics of the mutual interactions between bubbles, FFA and albumin, the amount of FFA is the limiting factor.
TC/HDL ratio as predisposing factor.
The TC/HDL ratio is an indicator for the condition of the arterial endothelium. A high ratio will be related to high numbers of crevases. This will result in more microbubble generation and consequently a higher VGE after a dive.

Study objective

Main objectives: Establishing the effect of BF as predisposing factor for the development of VGE and hence DCS by using subjects with a restricted range in age and VO2max. Establishing the effect of TC/HDL ratio and FFA as predisposing factors for the development of VGE.

Study design

The design can be described by distinguishing in the following parts or subsequent steps of execution.
1. Selection of subjects on the basis of the data of the obligatory dive-medical examination (navy divers) or the data of a questionnaire (recrational and professional divers)
2. Division of the divers in two equal age&VO2max matched groups.
3. The day before the simulation the divers are not allowed to perform physical exercise, or using stimulating liquids and drugs etc. No diving is allowed 3 days in advance of the dive-simulation.

4. After rising in the early morning, the divers take liquid (in amounts dependend on corrected body weight). Blood is sampled in the early morning (empty stomach) before the simulation. BF% is determined with the bio-impedance method as control of the skinfolds method, known from the data of the obligate medical dive-examination of the examination-physician (with approval of the diver).
5. A standardized breakfast, either fat-poor (the one group) or fat-rich (the other group) with liquid intake is used an hour before the simulation (both dependend on corrected body weight).
6. Dry dive *simulation in the morning to 21 m equivalent depth for 40 min in total.
7. Blood sample directly after simulation (FFA).
8. Doppler measurements during 2h20min after *surfacing*.

Study burden and risks

Risks assessment, group relatedness
The risks associated with the dive simulation can be considered as very low (2.0%). Due to the small depth and other conditions of the simulation, DCS when occurring will be mild. DMC is THE authority to treat DCS of offshore and recreational divers and caisson workers, in addition to navy divers. With their experience and on the basis of knowledge of other dive medical centres (navy and commercial) the risk of remaining symptoms and permanent damage is expected to be very small (ca. 2% of the treated DCS cases).
The burden of the simulation can be considered minimal, compared to a real, wet 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

passed the for divers obligatory medical dive-examination
male, non smoking
40-50 years old
50 ml.min.kg>VO2max>35 ml.min.kg

Exclusion criteria

following from D4a
frequently unable to equalize middel ear
claustrofobia
smoking

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	27-04-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL31231.018.10