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The effect of air or enriched air nitrox breathing during simulated diving on intravascular bubble formation following decompression

Submission date
24/02/2016

Recruitment status
No longer recruiting

Registration date
25/03/2016

Overall study status
Completed

Last Edited
25/04/2023

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Decompression sickness is an uncommon but serious complication of diving. It occurs when hyperbaric (high pressure) conditions during diving lead to bubbles of nitrogen forming in the blood vessels upon decompression (when the diver ascends from depth). Decompression sickness can produce many symptoms, ranging from joint pain and rashes to paralysis and death. Breathing gas mixtures with less nitrogen and higher oxygen content may decrease bubble formation after decompression. This study aims to investigate whether enriched air nitrox reduces bubble formation during simulated diving as compared to breathing normal air.

Who can participate?
Healthy volunteers aged over 18 with a diving license and without a history of a decompression accident.

What does the study involve?
Participants perform a simulated dive breathing air in the hyperbaric chamber of the CHU d' Angers. Intravascular bubble formation is assessed after the dive using cardiac (heart) ultrasound. Twelve participants prone to bubbling are then selected to perform two more simulated dives, one dive breathing air and the other dive breathing enriched air nitrox. Cardiac ultrasound is performed after each dive.

What are the possible benefits and risks of participating?
There are no benefits for the volunteers. Possible side-effects include decompression symptoms, similar to a non-simulated dive. All volunteers will be accompanied by a physician certified in hyperbaric medicine during a simulated dive.

Where is the study run from?
Centre Hospitalier Universitaire d'Angers (France)

When is the study starting and how long is it expected to run for?
January 2001 to August 2007

Who is funding the study?
Investigator initiated and funded (France)

Who is the main contact?
Prof Pierre Asfar

Contact information

Type(s)
Scientific

Contact name
Prof Pierre Asfar

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of bubble formation after diving with air or nitrox using cardiac ultrasound (Comparaison par echocardiographie Doppler du phenomene bulleux a l’issue d’une plongee a l’ air et au nitrox)

Acronym
NITROX

Study objectives
Enriched air nitrox reduces venous bubble scores as compared to air breathing during diving, and thereby the risk of decompression sickness in volunteers selected for high post-decompression bubble formation.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Committee for protection of human subjects in biomedical research of Pays de la Loire (Comité consultatif de protection des personnes dans la recherche biomédical des Pays de la Loire), 23/11 /2001, Protocol number 2001/17

Study design
Single-center prospective double-blind study with crossover design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Decompression illness in hyperbaric medicine

Interventions
The 47 divers underwent an initial simulated air dive to exclude subjects with low intravascular bubble production (Bubble score ≤ 1) in order to select divers with high bubble production (Bubble score ≥ 2). Twelve divers (10 men and two women) demonstrating high intravascular bubble production completed the study protocol in a randomized, double-blinded crossover setup. Divers were assigned to undergo one simulated dive while breathing air (Air; 21% oxygen) and one simulated dive breathing enriched air nitrox (EAN) with 36% oxygen in a randomized order.

Intervention Type
Other

Primary outcome measure
Pulsed Doppler measurements of the trunk of the pulmonary artery in order to quantify intravascular bubble formation. Measurements of at least 1 minute duration were performed by a certified cardiologist, blinded for the FiO2 at 0, 30, 60 and 90 minutes after decompression. Images were recorded and analyzed for bubble scores offline. A modified bubble score was used, based on the Doppler score system of Spencer. Bubbles scores were analyzed independently by two blinded reviewers.

Secondary outcome measures
Decompression incidents by questionnaire 90 minutes after completion of the simulated dive.

Overall study start date
01/01/2001

Completion date
10/08/2007

Eligibility

Key inclusion criteria
1. Forty-seven human volunteers
2. Age >18 years
3. Diving experience as confirmed by possession of a French recreational diver license
4. Absence of contraindication to dive

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
18 per group in randomized phase. No specification for number of participants for test dive was indicated in the study protocol.

Total final enrolment
12

Key exclusion criteria
1. History of decompression accident(s)
2. Oxygen administration or diving within 24 hours before simulated dive
3. Absent or low intravascular bubble production (Bubble score ≤ 1) after initial simulated test dive

Date of first enrolment
03/07/2002

Date of final enrolment
10/08/2007

Locations

Countries of recruitment
France

Study participating centre
Centre Hospitalier Universitaire d'Angers
4 Rue Larrey
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France
49933

Sponsor information

Organisation
Centre Hospitalier Universitaire d'Angers (France)

Sponsor details
4 Rue Larrey
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0250ngj72

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (France)

Results and Publications

Publication and dissemination plan
The manuscript containing the trial results has been submitted for publication

Intention to publish date

30/09/2016

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/05/2016		Yes	No
Protocol (other)		10/05/2016	25/04/2023	No	No