THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

Participant Information Sheet

Study title: *Gas narcosis in hyperbaric environments*

Locality:		Ethics committee ref.:	***16/NTA/93***
Lead investigator:	*Xavier Vrijdag MSc.*	Contact phone number:	*09 923 9300*

You are invited to take part in a research study (called the gas narcosis study) investigating the narcotic effects of several common gasses during diving. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Purpose of the study

During diving the gasses you breathe might become narcotic at certain depths. All divers have learned about nitrogen narcosis. In this study we will investigate the narcotic effects of nitrogen as well as oxygen, and helium. Although carbon dioxide is not a breathing gas, its levels in the body can change during diving and we will also investigate its role in causing narcosis.

To do this, we will analyze the electrical signals of your brain activity (EEG) using a computer program that we will make during part 1 of this study. In part 2 we will use the EEG computer program to measure nitrogen narcosis, and in part 3 we will determine whether oxygen can also produce narcosis. In the last part of this study we will determine the narcotic effect of carbon dioxide. We will also investigate if high levels of carbon dioxide make nitrogen narcosis worse. With this information divers can choose the safest gas mixture for the dives they make.

The study is funded by the Office for Naval Research of the US Navy. The study is performed by the Department of Anesthesiology of the University of Auckland and has received ethical approval from Northern A/B Health and Disability Ethics Committee (Ref: 16/NTA/93).

What will my participation in the study involve?
The study consists of four parts. You can choose to participate in a single part, all four parts or in any combination of the four parts.

During the first visit we will confirm you are suitable for participation in the study. This will involve completing a short questionnaire about your health and habits. You must be between 18 and 55 years of age, a certified diver, and currently fit for diving (which we will help assess). You will not be suitable if you are currently using recreational drugs, consuming more than 21 standard alcoholic drinks in an average week, currently smoking, suffering from any medical condition that affects judgment, or you regularly take any psychoactive medication including antihistamines. You will also complete the same Recreational Scuba Training Council screening questionnaire for fitness for diving that you would have completed prior to open water training. Any information you disclose during this visit will remain strictly confidential and known only to the coordinating investigator and one of the diving medical doctors involved.

During the first visit we will also explain the study procedures and answer all the questions you may have. If you agree to participate we will ask you to sign the informed consent form at the end of this document. We will introduce you to the tests used in this study. The first two tests are “thinking function” exercises completed on a tablet. The last test is a measurement where you look at a small light and judge if it flickers or not.

In this study we will measure your brain activity. We will place a cap containing electrodes (sensors) on your head. These rest on your scalp. During each measurement we will ask you to lay still with your eyes closed, while we will measure your brain activity. After this you will perform the tests we trained you for in the first visit. If you participate in the first part of the study you will breathe three concentrations of nitrous oxide (laughing gas) at the “surface” (1 Atmosphere pressure), while we measure your brain activity and ask you to do the tests we trained you for in the first visit. This visit will take approximately 4.5 hours.

Parts 2, 3 and 4 will partly take place in a hyperbaric chamber.

In part 2, you will make two compressions in the hyperbaric chamber. Both compressions will first stop at 3.5 Atmospheres (25 meters of seawater equivalent) and then continue to 6 atmospheres (50 meters equivalent). At 3.5 and 6 atmospheres you will undergo measurement of brain activity and complete the tests described earlier. During one compression you will breathe air, and during the other you will breathe a mixture of helium and oxygen (heliox). For this part you will visit the research center 2 times. Each visit will take approximately 3.5 hours.

Part 3 consists of one hyperbaric chamber compression which first pauses at 1.4 atmospheres (4 meters equivalent) and then continues to 2.8 atmospheres (18 meters equivalent). You will breathe 100% oxygen during the dive. At both depths you will undergo measurement of brain activity as described earlier. This will take approximately 2 hours and 15 minutes.

Part 4 involves one session at the “surface” (1 atmosphere), and then two sessions in the hyperbaric chamber which will be compressed to 6 atmospheres (50 meters equivalent). In the first session you will breathe heliox at the “surface” with inspired carbon dioxide titrated to achieve 3 different target levels of carbon dioxide in your exhaled breath. At each of the target levels you will undergo measurement of brain activity as described earlier. In the following 2 sessions you will be compressed to 6 atmospheres (50 meters equivalent) breathing with either air (1 session) or heliox (the other session). As in the first session we will introduce sufficient carbon dioxide to the breathing gas to achieve 3 different target levels of carbon dioxide in your exhaled breath and you will undergo measurement of brain activity at each of these target levels. For this part you will visit the research center 3 times. The first visit will take approximately 3.5 hours and the other two 7 hours.

Risks & Benefits

Participating in this study is of no direct benefit to you. However, the information we collect may assist us to make diving safer in the future, benefitting all divers. Many divers find participation in this type of research to be very interesting. We believe that the risks in participating in this study are very low. Breathing nitrous oxide in the first part might cause nausea and vomiting. We designed the protocol to minimize this and we are able to give you medication to treat it. The exposures to pressure in the hyperbaric chamber can potentially result in ear/sinus squeeze, oxygen seizure (approximately 1 in 1000 chance) and decompression illness (approximately 1 in 10.000 chance) just as in real diving. In the protocol we use for these dives we minimize the exposure to minimize these risks. Decompressions will be according to the Canadian Navy tables with the shallow oxygen stops padded for safety. You will be under the direct supervision of the investigators and doctors at all times during the experiments. We will check you are well when you leave the facility after the experiment. In the highly unlikely event you might get injured during the experiment we will provide you with optimal treatment directly during your visit or whenever necessary after your visit. If you believe you have any problems that might have a relation with your participation in this study you can contact the investigator directly with the contact details provided at the end of this sheet. During this study we will not access your medical records. However, if you get injured during the experiment the treating physician might access your medical records to treat you in the best way possible.

Who pays for the study?

There are no costs involved to participate in this study. You can receive a reimbursement for any travel costs you incur for participating in this study.

What if something goes wrong?

If you were injured in this study, which is unlikely, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

What are my rights and what happens after the study?

If you do want to take part now, but change your mind later, you can pull out of the study at any time. There will be no disadvantages for you, if you change your mind. No information, which could personally identify you, will be used in any reports on this study. All information collected from you will be kept confidential and coded only by a randomly assigned study number. It will be stored in a secure manner by the Department of Anaesthesiology of the University of Auckland for a period of 10 years. Only the research staff involved with this study will have access to the study data. At any time during or after the study you are able to access the information we collected about you as part of this study.

The study will end in September 2019. If you wish, you will receive information regarding the results of this study. The results of this study will be published in medical journals and in diving magazines.

Contact information

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Xavier Vrijdag, Lead investigator
09 923 9300
x.vrijdag@gmail.com

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

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Consent Form

I have read and I understand the Participant Information Sheet.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time.
I consent to the research staff collecting and processing my information, including information about my health.
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
I consent to my GP being informed about any significant abnormal results obtained during the study.
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my medical information for the sole purpose of checking the accuracy of the information recorded for the study.
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
I understand the compensation provisions in case of injury during the study.
I know who to contact if I have any questions about the study in general.
I understand my responsibilities as a study participant.
I wish to receive a summary of the results from the study. Yes ☐ No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:
I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it. I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____