UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM

Protocol Title: Pseudoephedrine Prophylaxis for Prevention of Middle Ear Barotrauma in Hyperbaric Oxygen Therapy

Study No.: HP-00090947 NCT04332211

Principal Investigator: Siamak Moayedi, MD. Telephone: (410) 328-6152

Sponsor: University of Maryland Department of Emergency Medicine

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CONCISE SUMMARY:
This is a voluntary research study evaluating whether pseudoephedrine (Sudafed) will help prevent ear pain during hyperbaric therapy. Because you are a patient scheduled to receive hyperbaric oxygen therapy (HBOT), we would like your consent to help with this study.

Prior to your HBOT session, we will give you an unlabeled pill to take. This will be either a placebo (fake) pill or a pseudoephedrine pill in order to compare effects on preventing ear pain.

The risks of the study include middle ear pain from the hyperbaric oxygen therapy, as well as potential side effects of pseudoephedrine such as headache, restlessness or irregular heartbeats. However, pseudoephedrine is a commonly used over-the-counter medication, and we will have screened you for any significant heart-related risk prior to this study.

If you are interested in learning more about this study, please continue to read below. Additionally the study is registered with clinicaltrial.gov and you can find more information by looking up title of the study.

PURPOSE OF STUDY
We are comparing the use of pseudoephedrine to placebo in preventing middle ear trauma during hyperbaric oxygen therapy. You will be one of up to 105 participants who will be enrolled in this study.

PROCEDURES

We will check your blood pressure and heart rate prior to enrollment of the study. Before you begin your hyperbaric oxygen therapy, we will give you an unlabeled pill sometime between the time period of 45 minutes before your session and within 120 minutes of the session beginning. Neither you nor the researchers will be aware of which pill you are given.
The hyperbaric physician on duty will examine your ears prior to the therapy session to look for any pre-existing ear trauma.
During the therapy, a nurse inside the chamber will ask you if you have any ear pain on the scale of 1 to 10, 10 being the most severe pain. This information will be shared with the researchers

outside the chamber for them to document. The researchers will be outside the chamber to record the need to stop the therapy due to any ear pain and provide a rescue medication for pain relief if needed.
Once the therapy is completed, the hyperbaric physician will again examine your ears for follow-up. There are no additional tests required for this study after completion of your therapy session and ear examination. The duration of your involvement will be dependent on the length of your HBOT session. If you are unable to complete your therapy session, we will document the reason and end your participation in the study.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible for taking the provided unlabeled pill, informing us of any ear pain during your HBOT session, and allowing us to examine your ears before and after the therapy.

POTENTIAL RISKS/DISCOMFORTS:

You may experience ear pain during HBOT. The nurse inside the chamber will be monitoring you during the session, and the research assistants will be outside the chamber to stop the therapy and provide rescue medication for any ear pain. If you experience any other reason for stopping your HBOT, we will end the study session.

Pseudoephedrine is a common over-the-counter medication used for decongestion but may be associated with side effects including restlessness, nausea, vomiting, headache, dizziness, stomach pain, difficulty breathing and irregular heartbeats. The attending nurse and hyperbaric physician, as well as the research assistants, will be monitoring you for any discomforts.

POTENTIAL BENEFITS

By helping with this research, you may experience reduced ear pain and trauma from taking pseudoephedrine. Ultimately, your participation will help future HBOT patients by helping to prevent ear pain/trauma.

PAYMENT PARTICIPANTS

There is no payment for participation.

ALTERNATIVES TO PARTICIPATION

Participation is completely voluntary. You may choose not to participate and even change your mind at any point even after signing this consent form.

COSTS TO PARTICIPANTS

It will not cost you anything to take part in this study.

CONFIDENTIALITY AND ACCESS TO RECORDS

We will not collect your name or medical record number. Efforts will be made to limit your personal information, including your age, gender, smoking history, sinus disease, airplane flight

history and current nasal congestion, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the study team member who is with you in the electrophysiology lab. If you withdraw from this study, already collected data may not be removed from the study database. If you have questions, concerns, or complaints, please contact the investigator Dr. Moayedi at (410) 328-6152.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this project, UMB and/or one of its affiliated institutions or health care groups will help you obtain medical treatment for the specific injury and provide referrals to other health care facilities, as appropriate. UMB and/or its affiliated institutions or health care groups will not provide you with financial compensation or reimbursement for the cost of care provided to treat a research-related injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. If you incur uninsured medical costs, they are your responsibility. The study staff can give you more information about this if you have a study injury.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Participant:_____

Date of Birth: _____ **Medical Record Number:** _____

NAME OF THIS RESEARCH STUDY: *Pseudoephedrine Prophylaxis for Prevention of Middle Ear Barotrauma in Hyperbaric Oxygen Therapy*

UMB IRB APPROVAL NUMBER: *HP-* 00090947

RESEARCHER'S NAME: *SIAMAK MOAYEDI, MD*

RESEARCHER'S CONTACT INFORMATION:

UMMC Center for Hyperbaric and Dive Medicine
22 S. Greene St. Ground Floor, West Elevator
Baltimore, MD 21201
(410) 328-6152

This research study will use health information that identifies you. If you agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- Age
- Sinus disease past medical history
- Smoking history
- Any current nasal congestion

Federal laws require this researcher to protect the privacy of this health information. He/she will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. Siamak Moayedi and his research team.
- The sponsor of the study, or its agents, such as data repositories or contract research organizations

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.
To revoke this Authorization, send a letter to this researcher stating your decision. He/she will stop collecting health information about you. This researcher might not allow you to continue in this study. He/she can use or share health information already gathered.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you receive at:
    - University Physicians, Inc. (UPI)
    - University of Maryland Medical System (UMMS)

  It will not cause any loss of benefits to which you are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, UPI, UMMS to give it to them.
- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, UPI, UMMS.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask this research how to get a copy of this information from him/her.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to share my protected health information with this researcher for the purposes described above.

Signature: _____Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your/your child's rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.