Informed Consent

Protocol: Hyperbaric Oxygen Therapy to Prevent Complications after Lower Limb Amputation

NCT #: NCT04717557

Date: September 25th, 2023

Form
M0345

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study:
Hyperbaric Oxygen Therapy to Prevent Complications
after Lower Limb Amputation

Concise Summary

The purpose of this study is to determine whether hyperbaric oxygen therapy decreases complications after lower leg amputation. Such complications include wound infection, additional surgeries and readmission to hospital after discharge. We are also seeking to determine whether hyperbaric oxygen therapy administered in the days following amputation will decrease the required number of days in hospital.

If you participate in this study you will randomly be selected (using a technique similar to the flip of a coin) to receive either twice daily hyperbaric oxygen therapy or usual care. If you are selected to receive hyperbaric oxygen, each treatment will consist of breathing 100% oxygen through a head tent while inside a hyperbaric chamber compressed to 2 times normal atmospheric pressure, for slightly more than 2 hours.

Hyperbaric oxygen has a good safety record, however there are some risks. With compression there is occasional difficulty getting the air pressure in the ears, sinuses, teeth, lungs, and intestines to equal the increasing pressure outside the body. Such problems may cause pain and the movement of blood and fluid into these spaces. Hearing loss, inflammation of the ear and sinuses may occur. Usually, these symptoms are temporary and resolve within a few days. Very rarely do permanent problems occur. Exposure to higher than normal oxygen concentrations can cause generalized shaking and seizures. Some patients undergoing these repeated exposures to elevated levels of oxygen have been noted to develop blurred vision at a distance (near sightedness) after 20-30 exposures. This loss has lasted for the remainder of the exposures and for 1-2 months afterwards. At the Duke Hyperbaric Center there have been no serious complications.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you are undergoing surgery to remove part of your leg or foot (amputation). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Chandler Long and Dr. Richard Moon will be your doctors for the study and will be in contact with your regular health care providers throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to better understand if giving people a treatment called Hyperbaric Oxygen Therapy helps them heal after this type of surgery and avoid complications from surgery. These treatments will be done here at Duke in the chambers at the Center for Hyperbaric Medicine and Environmental Physiology. These Chambers can be used to increase atmospheric pressure inside the chambers by pumping in air. Administering

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100% oxygen inside a hyperbaric chamber causes the oxygen level in the blood and tissues to increase. This study is designed to see what benefits this increased oxygen in the blood might have on improving patients' recovery from surgeries like the one you will have.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 140 people will take part in this study at Duke University Hospital.

WHAT IS INVOLVED IN THE STUDY?
If you agree to take part in the study the you are agreeing to the following:

1. Receive hyperbaric oxygen treatments while in the hospital after surgery
2. Have information from my medical record included in the study records once personal identifying information is removed.
3. Have non-invasive studies performed in addition to those that may occur during the normal course of my care. These non-invasive studies consist of measurements of oxygen levels in my tissues at the site of my surgery (transcutaneous oxygen levels). This test consists of placing sensors on the skin near your wound, and one sensor on your chest. After a few minutes the readings will be reperated while you breathe oxygen via a face mask.
4. Follow-up phone calls after discharge from hospital.

This study is entirely voluntary and you may opt out at any time. You do not have to participate in this study to receive the same care that any patient recovering from surgery would receive.

Hyperbaric Oxygen Treatment involves going into a large chamber with other patients and hospital staff. The chamber is then pressurized to simulate depth under the sea. You will be given a clear plastic hood that allows you to breathe 100% oxygen. By going into the chamber and being under pressure the relative amount of oxygen in your blood will increase. This increased oxygen in your blood has been shown to cause changes in the way the body functions especially in response to healing and dealing with infection. Each treatment lasts approximately 2 ½ hours. You may receive treatments 1-2 times per day.

If you agree to be in this study, you will be asked to sign and date this consent form. When you agree to participate in this study you will be randomly assigned to one of two groups. Either you will be assigned to the group that breathes 100% oxygen in the chamber in addition to regular care or to the group that receives regular care only.

Your care otherwise will be the same as you would otherwise receive if you did not take part in this study. You may choose to leave the study at any time by telling your treatment team you do not want to take part. They will notify the study staff and you will continue to receive the same care you otherwise would have, but you will not go back into the chamber.

HOW LONG WILL I BE IN THIS STUDY?
This study will take place over the course of two years. Most of the study is taking place while you are in the hospital, and you will not receive treatments for longer than a few days, but you may be asked questions at future doctor's visits or your medical records may be reviewed for as long as two years.

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You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
The Chambers at the Center for Hyperbaric Medicine and Environmental Physiology can be used to increase atmospheric pressure inside the chambers by pumping in air. Exposure to such an atmospheric pressure change will involve changes in pressure both inside and outside the body.

Potential hazards with such exposures are:

1. Hazards associated with compression or increasing the air pressure inside the chambers (simulation of depths below the sea)

> Most Likely: with compression there is occasional difficulty getting the air pressure in the ears, sinuses, teeth, lungs, and intestines to equal the increasing pressure outside the body. Such problems may cause pain and the movement of blood and fluid into these spaces. Hearing loss, inflammation of the ear and sinuses may occur. Usually, these symptoms are temporary and resolve within a few days. Very rarely do permanent problems occur. Ear pressure difficulties occur in approximately 1 out of 5 patients. Temporary hearing loss, problems equalizing sinus pressure are much less common, approximately 1 out of 100 patients.
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> Less Likely: Occasionally, individuals have air filled cysts in their lungs. If such a person is exposed to increasing pressure, the cyst could possibly rupture and cause the lung to collapse, requiring medical and/or surgical treatment such as inserting a tube through the skin into the chest to re-expand the collapsed lung. This problem has never happened at Duke.
>
> There are no known hazards of transcutaneous oxygen measurement.

2. Hazards associated with exposures to high oxygen levels.

> Less Likely: Exposure to higher than normal oxygen concentrations can cause generalized shaking and seizures (at Duke 1 out of 3,000-4,000 treatments). Some patients undergoing these repeated exposures to elevated levels of oxygen have been noted to develop blurred vision at a distance (near sightedness) after 20-30 exposures. This loss has lasted for the remainder of the exposures and for 1-2 months afterwards. During this time, if you wish to drive a car or see normally at a distance, it will be necessary to wear glasses. If you already wear glasses you may need a new prescription. Vision usually returns to the same level it was prior to treatment 2-3 months after the last treatment, but not always. Rarely, near sightedness persists indefinitely (less than 1% of patients).

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3. Risks associated with equipment failure.

Less Likely: If there is mechanical or electrical failure of part of the pressure tank or of equipment, which keeps it operating safely, the exposed humans could be seriously harmed or even killed. If a fire occurs within the pressure tank, all exposed humans could be burned or asphyxiated. While remote, nonetheless, the possibility of equipment failure cannot be entirely eliminated. In over 50 years of experience, there have been no instances of serious structural failure.

During many years in which transcutaneous oxygen measurement has been used in this facility, no side effects have occurred.

4. Pregnancy

Evidence demonstrating the untoward effects of hyperbaric oxygen on the unborn fetus is not clear. It is in the best interest of the unborn child not to be put at any increased risk of injury. For women of childbearing potential, a pregnancy test will have been performed before surgery.

If you are a woman who could possibly become pregnant (you have not had a hysterectomy and/or both tubes and/or both ovaries removed) and you have a partner who is able to father children, you and your partner must agree to either abstain completely from vaginal intercourse until the hyperbaric sessions are concluded or use a highly effective method of contraception for the same length of time. Highly effective methods include (a) partner vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices (IUDs), (d) hormonal implants (such as Implanon), or (e) other hormonal methods (birth control pills, injections, patches, vaginal rings). If you and your partner are not currently using one of these methods your study doctor will discuss options with you, given your medical condition, your personal preferences, and the level of effectiveness required for this study. Because no birth control method is 100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant, even if you have had a recent negative pregnancy test.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefit to you. You may heal faster, have less risk of infection, and recover from surgery more effectively. We hope that in the future the information learned from this study will benefit other people with your condition.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of this study any tests, x-rays and/or procedures would have been done as part of your regular care. The study doctor will record these test results both to treat you and to complete this research. These test results will

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be recorded in your medical record and will be reported to the study administrators. Results of tests and studies done solely for this research study and not as part of your regular care will be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

Some information collected in research studies is maintained in your medical record. However, for this study that information will be inaccessible until the end of the study, unless your physician(s) decide that it is necessary for your care.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

WHAT ARE THE COSTS TO YOU?

There is no additional cost to you for participating in this study. You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

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WHAT ABOUT COMPENSATION?
You will not be compensated for your participation in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Duke Center For Hyperbaric Medicine & Environmental Physiology at 919-684-6726 during normal business hours or 919-684-8111 during emergencies and ask to speak with Dr. Richard Moon.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. The Food and Drug Administration may inspect the records.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, in order to let them know that you are withdrawing from the study we ask that you contact Dr. Richard Moon in person or in writing at:

Duke Center for Hyperbaric Medicine & Environmental Physiology
Trent Dr., Building CR2 Room 0584, Box 3823, DUMC
Durham, NC 27710

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include: you need ICU care, you have an adverse reaction to the hyperbaric oxygen treatment, you become pregnant, your treatment team decides it's not safe to have you continue with the hyperbaric oxygen treatments.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Richard Moon at 919-684-6726 during normal business hours or 919-684-8111 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time