INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Measurement of Oxygen Saturation in healthy human volunteers before, during and after hyperemic events using Multi-Modal Techniques: Spatial Frequency Domain Imaging (SFDI), transcutaneous oxygen measurement (TCOM), Pulse Oximeter, and Apple Watch.
Sponsor: Department of Surgery

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

STUDY SUMMARY

Pulse oximeters are commonly used medical devices to measure blood oxygen saturation. With recent advances in technology, Apple Watch and transcutaneous oximetry (TCOM) now have capabilities similar to pulse oximetry. Since it is possible that most people could utilize this technology, the researchers wish to assess the accuracy, reliability and usability of these oximeters and compare outcomes. In this study, 20 volunteers will be tested using these devices, and we will compare the data to identify which options are reliable for skin oxygen measurement.

Please review the rest of this document for more details about this study and the things you should know before deciding whether to participate in this study.

WHY IS THIS STUDY BEING DONE?

The reliability of the oxygen monitoring is key to monitor and diagnose people's oxygenation level. Several oxygen measuring and mapping devices have been developed and are in use. The researchers seek to investigate and compare the ground reality of the accuracy and reliability of other oxygen measuring equipment compared to the Pulse Oximetry in a small cohort of a healthy volunteers.

The research team are asking you if you want to be in this study because you are a healthy candidate that either works at Indiana University or IU Health so the study visit location is convenient to you. The study is being conducted by PI: Dr. Surya C. Gnyawali of Indiana University, Department of Surgery.

WHAT WILL HAPPEN DURING THE STUDY?

First, you will go through a questionnaire session about your medical history by a designated study team member. If you consent to participate in the study, you will be enrolled and you will then do the following testing with staff assistance:

Spatial Frequency Domain Imaging (SFDI): During this phase, the equipment will be adjusted and setup ready for scanning. Your thumb along with the palm of your hand will be scanned. Actual scanning takes less than 60 seconds. The images will be processed offline to obtain the oxygen data.

Transcutaneous oxygen monitoring (TCOM): Transcutaneous oximetry (TCOM) is a noninvasive test that directly measures the oxygen level of tissue beneath the skin. Because oxygen is carried to tissues by blood flow in the arteries, TCOM is an indirect measure of blood flow. This test is often used to evaluate advanced peripheral arterial disease, a condition in which blood flow to an extremity is greatly reduced. The area to be tested (your thumb) is first cleaned with alcohol. A gel that conducts electrical impulses is applied, and then the study team member places adhesive sensors containing a platinum electrode that can sense oxygen on the affected limb.

Electrodes in the sensors heat the area underneath the skin to dilate (widen) the capillaries so oxygen can flow freely to the skin, providing an optimal reading. This takes about 15 minutes. The readings are converted to an electrical current and the signal is displayed on a monitor and recorded. Once the test is completed, the sensors are removed, the testing sites are cleaned. Transcutaneous oximetry has no known side effects or complications.

Apple Watch Oxygen Sensor: The Apple watch sensor will be positioned on the wrist surface and data will be recorded.

Pulse Oximeter for Oxygen Monitoring: The pulse oximeter enables transcutaneous (through skin) monitoring of the oxygen saturation of red blood cells. In this study, your thumb will be used to measure your blood oxygen saturation level. Your thumb will be sandwiched within this device for about 6 seconds to get the reading, you will remain still during this time to ensure an accurate reading. As this reading can be impacted by nail polish, we ask that after enrollment, polish is removed if applicable. This device has a soft silicone in the finger chamber to minimize discomfort.

For each study task:

- The tasks listed above will be completed near the thumb, index finger, or wrist.
- The series of tasks will be performed 3 times: once as a baseline, once with a blood pressure cuff inflated around the arm, and once after the cuff has been deflated.
- The expected amount of time for each procedure will be 5-15 minutes and visit will last up to 2 hours
- The procedure is purely experimental

You will receive the results of any of these tests if you want to after the finishing of the research study.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

The possible risks include skin irritation or discomfort from the electrodes or even the watch strap. There is a minimal risk of pain from the inflation of the blood pressure cuff. The pulse oximeter may be snug on your finger causing you to feel pressure. All devices, except the Apple Watch are clinically used and are non-invasive. There is a risk of loss of confidentiality which the research team will ensure your data is in a locked and secured location to reduce this risk.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

You will be able to know your oxygen level after this study. In addition, we hope to learn things that will help other people in the future.

WILL I BE PAID FOR PARTICIPATION?

You will not be paid for participating in this study.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION BE USED?

The following individuals and organizations may receive or use your identifiable information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - The United States Food and Drug Administration (FDA)

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies .

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the PI: Dr. Surya Gnyawali, at 614-371-2027. For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not at all affect you.

PARTICIPANT'S CONSENT

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

Participant's Printed Name: _____

Participant's Signature:_____**Date:**_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date:**_____