

Western Medicine & Dentistry Division

of

800 Commissioners Rd East • London, Ontario • N6A 5W9 • Canada
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Emergency Medicine

Title of Project: Calibration and Validation of Low-Cost 3D Printed Pulse Oximeter

Principal Investigator: Dr. Tarek Loubani, MD, CCFP (EM)

Co-Investigators: Dr. Melanie Columbus, PhD, Mrs. Kristine Van Aarsen, MSc

Background & Purpose

You are invited to participate in a research study to calibrate a low-cost 3D printed pulse oximeter. A pulse oximeter is a sensor device placed on the finger to measure oxygen levels in the blood. All emergency department patients and adults over the age of 18 are eligible to participate in this study. This letter contains information to help you decide whether or not to participate in this research study. It is important for you to understand why the study is being conducted and what it will involve. Please take the time to review it carefully and feel free to ask questions if anything is unclear or there are words/phrases that you do not understand.

The purpose of this study is to calibrate and validate a low-cost 3D printed pulse oximeter that measures oxygen levels in the blood.

Calibration is the process by which data is collected from a pulse oximeter and another method (blood sampling from your artery) so that the raw data from the pulse oximeter can be translated into clinically usable values (percent of oxygen in a patient).

Validation is the process by which the calibration process is checked to ensure that the end-result (the oxygen values) are accurate when compared to a gold standard device.

Measurements from the experimental pulse oximeter will be compared to a gold standard – the pulse oximeter currently used in the emergency department at London Health Sciences Centre (LHSC). The experimental pulse oximeter can be manufactured at a fraction of the cost of currently employed devices and may be a cost-effective alternative for hospitals and clinics in both the developed and developing worlds.

You are being asked to help validate a new low-cost 3D printed pulse oximeter. This means that the data taken from you will be used to verify equations taken in a previous phase to ensure the pulse oximeter is outputting accurate and clinically useful values. Your participation in the study involves completion of the study protocol. All study procedures will be conducted in the emergency department at Victoria Hospital and University Hospital at LHSC by an experienced emergency physician (EP). 350 participants will be recruited to examine the validity of the calibrated experimental pulse oximeter. The experimental and control pulse oximeters will be placed on two different fingers on the same hand. Measurements of oxygen saturation will be recorded to establish equivalence of the two oximeters. This study takes approximately 5 minutes to complete, is completely non-invasive, and will not interfere with regular clinical care.

This study is part of an unfunded research project being undertaken by Dr. Tarek Loubani of Western University. Should you require any further information, please feel free to contact: Dr. Tarek Loubani (tlouban@uwo.ca), Carrie Wakem (carrie.wakem@lhsc.on.ca) or Melanie Columbus (melanie.columbus@lhsc.on.ca) at 519-685-8500 ext 55014.

Risks & Benefits

There are no additional risks associated with wearing two pulse oximeters for the five minute duration of the study. You may not benefit personally from the study. Participation in this study will not impact your clinical course, academic status or employment. Results of this study may benefit society by validating a low-priced pulse oximeter whose design is freely available which may impact emergency rooms in both the developed and developing worlds. You will not be compensated for your participation in this study.

Participation in this study is voluntary. You may refuse to participate or withdraw at any point in the study without impact on your clinical course, employment or academic status. If you withdraw, any data collected may also be withdrawn at your request.

Confidentiality

Your results will be stored in a locked cabinet in a secure office, will be viewed only by members of the research team, and will be destroyed at the completion of this study. If the results of this study are published, your name will not be used and no information that discloses your identity will be released or published. You do not waive any legal rights by participating in this study. Data will be retained for a period of 15 years after publication in a secure place, after which time it will be disposed of in a secure manner (e.g. shredded or electronically deleted).

Qualified representatives of the following organizations may look at the study records at the site where these records are held, for quality assurance (to check that the information collected for the study is correct and follows proper laws and guidelines).

Examples include:

- Representatives of Lawson Quality Assurance Education Program
- Representatives of the University of Western Ontario Health Sciences Research Ethics Board that oversees the ethical conduct of this study

If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute, (519) 667-6649

Should you require any further information, please feel free to contact: Dr. Tarek Loubani (tlouban@uwo.ca), Carrie Wakem (carrie.wakem@lhsc.on.ca) or Melanie Columbus (melanie.columbus@lhsc.on.ca) at 519-685-8500 ext 55014.

Thank you,

Dr. Tarek Loubani, MD, CCFP (EM)
Assistant Professor
Schulich School of Medicine and Dentistry
Western University

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Division of Emergency Medicine

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Consent to Participate

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I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Participant Signature

Participant Name (Printed)

Date

Signature of Person
Obtaining Informed Consent

Person Obtaining Informed
Consent (Printed)

Date