London Health Sciences Centre

LAWSON HEALTH RESEARCH INSTITUTE

Division of Emergency Medicine

Western Medicine&Dentistry

Title of Project: Non-invasive positive pressure ventilation mask to minimize mask leak and potential aerosolization leading to spread of virus such as COVID-19

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

Co-Investigators: Dr. Scott Anderson, MD, FRCPC

Sponsor: Glia Project

Funding: Bassel Khartabil Fellowship awarded to Dr. Loubani. Additionally, masks have been provided in kind from General Dynamics.

Conflict of Interest: Dr. Tarek Loubani (PI) is the medical director of the Glia project, one of the companies that collaborated on research and development of this device. However, Dr. Loubani is not involved in decisions that can alter the study's outcome.

Background & Purpose

In this Consent document, "you" always refers to the study participant. If you are a substitute decision maker (SDM) (i.e. someone who makes the decision of participation on behalf of a participant), please remember that "you" refers to the study patient. If an SDM is needed for this study, you will be asked to review and sign this consent form on behalf of the participant.

You are being invited to participate in a research study because your physician has determined that you would benefit from non-invasive breathing support or you have already received such support. Our goal is to see whether or not a new mask and circuit has the ability to maintain non-invasive ventilatory (breathing) support while minimizing the amount of air that leaks around the mask.

Patients presenting to the emergency department, or needing hospitalization, for a variety of medical conditions often require non-invasive ventilation (breathing support) such as a bilevel positive airway pressure (BIPAP) or continuous positive airway pressure (CPAP) machine, which delivers pressurized air into the patient's airway. However, in the current environment of COVID-19, the aerosols (virus

particles in the air) produced by this machine leaking pose serious potential harms to healthcare providers and other patients.

All adult patients who present to the emergency department or who are admitted in hospital in a monitored or critical care setting requiring non-invasive ventilation will be invited to participate in this research study. It is important for you to understand why the study is being conducted and what it will involve or already has involved. Please take the time to review it carefully and feel free to ask any questions if anything is unclear or there are words/phrases that you do not understand.

The purpose of this study is to validate a BiPAP mask in its ability to maintain non-invasive ventilatory support while minimizing air leak around the mask that might cause aerosolization of viral particles. When a health care provider identifies that you require non-invasive ventilatory support for your current health condition, you will be fitted for an appropriate sized mask and randomized into either a standard or experimental mask. If you have already received this support, you were already randomized.

Measurements from the experimental mask will be compared to the standard mask used in London Health Sciences Centre (LHSC). Once the BIPAP mask has been applied, data will be obtained from your medical chart initially and again at the four-hour, twelve-hour, and twenty-four-hour mark. Data will include: Glasgow Coma Scale (GCS) which measures level of consciousness, vital signs, evidence of mask leakage, mask leak volumes, and blood gas values (arterial or venous). The bloodwork that will be obtained is standard blood work that would routinely be drawn due to your current health status. There is no additional blood work drawn for this study.

This device was developed using an accelerated development model to meet an immediate and urgent need related to COVID-19. As such, this device is being rapidly deployed to hospitals. While this device has not been as rigorously tested as usual, it will be closely monitored for safety by the primary investigator and the data and safety monitoring board. This is the first time this device has been used on human patients.

All study procedures will be conducted in the emergency department or monitored settings at Victoria Hospital or University Hospital at LHSC by an experienced physician (EP), Registered Nurse (RN), and Respiratory Therapist (RT). Fifty participants will be recruited in order to validate the experimental mask.

This study is part of a 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), Chelsea Darling (chelsea.darling@lhsc.on.ca) or Kristine VanAarsen (Kristine.vanaarsen@lhsc.on.ca) at 519-685-8500 ext 76089

Risks & Benefits

There are no known direct benefits to the participant.

Your time will be utilized in the initiation of the study. The experimental mask's comfort is not yet known and it may be less comfortable than the control mask. Registered Nurses and Respiratory Therapists may be convinced by the efficacy of the device before data is available and may take less personal protective measures with patients who have the experimental mask.

There will be no delay in initiation of non-invasive ventilation and no additional blood tests, physical exam procedures or activities undergone solely for research purposes. All tests, procedures and activities would be conducted by health care staff for the patient as part of the standards of care for all patients with non-invasive ventilation. In addition to your usual care, data will be collected and you will be randomized to one of the two groups in the study.

As per any research project there is always a risk of a breach of privacy.

Voluntary Participation & Withdrawal

Participation in this study is voluntary. You may refuse to participate or withdraw at any point in the study. Participants will be withdrawn from the study by the primary physician and/or primary investigator if they are unable to tolerate mask, unable to remain calm, become agitated or violent, or patients physical or emotional status deteriorates. If you withdraw from the study, any data collected may also be withdrawn at your request.

If you are being asked to consent after you have received non-invasive ventilation and you do not agree to participate: 1) If you are still receiving non-invasive ventilation with an experimental mask, the mask will be switched for a standard mask and standard of care will resume, and 2) your data will be withdrawn.

Alternatives to Participation

Patients who decline participation in this study prior to the initiation of treatment will continue to receive appropriate interventions based on physician judgement and patient goals of care. If non-invasive ventilation is part of your goals of care, the standard mask will be used to provide non-invasive ventilatory (breathing) support in a negative pressure care area with enhanced personal protective equipment (PPE).

Confidentiality

For the purpose of the study, your full name and hospital personal identification number (PIN) will be collected. Your data will be labelled only with a study ID and a separate master list will be the only link between the data and your identifiable information. Data 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.

Identifiable 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
  Representatives of Health Canada

This study is being conducted in collaboration with Glia. Glia is a medical device company dedicated to creating open source low-cost medical devices. Glia helped develop this mask and will help distribute it after validation. Dr. Tarek Loubani, primary investigator in the study, is also the sole owner of Glia.

Glia will not receive any data from this study, and no data will be stored with Glia. There will be no sharing of consent forms or other personally identifying information with Glia.

You do not waive any legal rights by participating in this study. If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036 or access the online form at: https://apps.lhsc.on.ca/?q=forms/patient-relations-contact-form

Should you require any further information, please feel free to contact: Dr. Tarek Loubani (tlouban@uwo.ca) or Chelsea Darling (chelsea.darling@lhsc.on.ca).

Thank you,

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

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 Substitute Decision Maker	Name of Substitute Decision Maker (Printed)	Date
_____	_____	_____
Signature of Person Obtaining Informed Consent	Person Obtaining Informed Consent (Printed)	Date