Western Medicine&Dentistry
Division of Emergency Medicine

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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. Ben Thomson, Dr. Azad Mashari

Background & Purpose

You are invited to participate in a research study to validate that an easy-to-produce, specifically engineered mask and circuit has the ability to maintain non-invasive ventilatory support while minimizing air leak 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 BIPAP or CPAP machine. However, in the current environment of COVID-19, the aerosols produced by this machine in a COVID-19 positive patient 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 are 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 for yourself or your loved one. 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.

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, initial data will be obtained and again at the four-hour, 12 hour, and 24 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.

The data that is taken from you will be used to validate the effectiveness of an experimental mask in providing ventilatory support while minimizing mask leak, which might reduce the risk of virus transmission to health care workers and other patients at risk.

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). 50 participants will be recruited in order to validate the experimental mask.

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), 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 minimal risks associated directly with this study as patients will not undergo any additional interventions for research purposes only. All tests, procedures, and activities related to non-invasive ventilation would be conducted by health care staff for the patient as part of the standard of care.

The primary benefit of this study is the ability to use non-invasive ventilation within an environment where health care providers might otherwise be unable to use it due to concerns about the spread of viral particles such as COVID-19. The use of non-invasive ventilation may reduce the number of days that a patient is on a ventilator or even prevent invasive ventilation. By reducing or preventing invasive mechanical ventilation, participants will face fewer risks known to be associated with mechanical ventilation such as pneumothorax, muscle wasting, and death. 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. 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 a patient is withdrawn from the study, any data collected may also be withdrawn at your request.

A patient that is arriving to the emergency department or whose condition deteriorates during hospital admission and requires non-invasive ventilation may be enrolled in the study with informed consent to be provided in a delayed fashion due to acute respiratory distress and deteriorating medical condition. Due to the current pandemic, substitute decision makers (SDM) are only in hospital in extenuating circumstances and obtaining consent from the SDM may delay appropriate care. In such cases, obtaining consent may be delayed until the SDM can be contacted or the patient is stable and able to provide consent. If the patient or SDM subsequently decline participation, their data will be removed.

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

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 Experience Office at LHSC at (519) 685-8500 ext. 52036 or access the online form at: https://apps.lhsc.on.ca/?q=forms/patient-experience-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

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