

Cuff Leak Test and Airway Obstruction in Mechanically Ventilated ICU Patients (COMIC): A Pilot Trial

Consent Form

NCT: Not applicable

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Informed Consent Form for Participation in a Research Study

Study Title: Cuff Leak and Airway Obstruction in Mechanically Ventilated ICU Patients (**COMIC**):
A Randomized Controlled Trial

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INTRODUCTION

This consent form is for the patient who is eligible to take part in this study. However, if the patient is incapable of providing consent due to the severity of her/his illness, the consent of a relative or other authorized representative (substitute decision maker) is sought. If during the Intensive Care Unit (ICU) stay, the patient becomes capable of providing consent, informed consent will be sought from the patient as a condition of his/her continued participation. Throughout this form, "you" means the person you are representing.

Before deciding to participate in this study, it is important that you read and understand the information in this consent form. If you have questions after you read this form, ask the research coordinator or your doctor. Do not sign this form until you are sure you understand it.

You are being asked to consider participating in this study because you have been admitted to the ICU and required assistance with breathing using a breathing machine (the ventilator). Before the breathing machine is removed, a cuff leak test is done at the bedside, to check if there is air movement around the breathing tube. This study is testing the benefit and harm of this common bedside test that is used before removing the breathing machine from patients who are ready to breath on their own.

Respiratory Therapist routinely perform the cuff leak test. This test helps the clinical team evaluate if air can pass around the breathing tube, however the accuracy of this test is uncertain as there have been no randomized controlled trials (RCT) examining this. We would like to assess whether we can do an RCT to compare communicating the results of the cuff leak test with the treating physician versus not communicating the results with the treating physician to determine the precision of this test and its impact on our patients.

If you agree to be involved in this study, you will be one of 40 patients locally. This study is being done by a group of clinicians who regularly do research in critically ill patients. Your decision is voluntary. Should you choose not to participate in this study, your care will not be adversely affected in any way.

PROCEDURES

If you agree to be in this study, you will be asked to read each page and sign this consent form. After you sign it, you will be randomly assigned to Group A: the cuff leak test results not shared with the treating physician or Group B: the cuff leak test results shared with the treating physician. The communication strategy will be picked by chance, like the flip of a coin. You will not be able to choose which one you receive. The chances of receiving either strategy are approximately equal.

Group A: cuff leak test results not shared with the treating physician: If you are randomized to this group you will have a cuff leak test performed once you are ready to breath on your own, before removing the breathing machine. The Respiratory Therapist **will not** communicate the results with the treating physician and will proceed with removing the breathing machine regardless the result of the cuff leak test.

Group B: cuff leak test results not shared with the treating physician: If you are randomized to this group you will have a cuff leak test performed once you are ready to breath on your own, before removing the breathing machine. The Respiratory Therapist **will** communicate the results with the treating physician and will proceed with removing the breathing machine if the cuff leak test was positive (air leak detected). If the cuff leak test was negative (air leak not detected), the treating physician may prescribe a medication and delay removing the breathing machine till the next day.

The study will also involve collecting basic personal health information about you (i.e. date of birth) and your medical history including conditions you have or have had in the past. Each day that you are in the study, we will review your records so that we can collect information up to the time when you are discharged from the ICU (e.g., vital signs, test results, medications and any notes from doctors and nurses who are caring for you).

POTENTIAL HARMS

Patients with a high chance of developing airway obstruction or narrowing of their airway will not be considered for this study. We will only approach patients whose treating physician considers them not to be at high risk for airway obstruction or narrowing of their airway. If you develop an airway obstruction or narrowing after removing the breathing machine, this could result in difficulty in breathing and while some patients will recover with medications, others may require assistance breathing with the breathing machine. This could occur in both groups regardless of the cuff leak test results (air leak detected or not detected).

As per usual care, the medical team will watch you closely to see if you have difficulty in breathing after the breathing machine is removed.

POTENTIAL BENEFITS

This study is designed to benefit society by gaining new knowledge. It is not possible to say if you will benefit directly from this study.

STOPPING THE STUDY

The study investigators or the representatives of the Research Ethics Board have the right to cancel the study at any time. If this happens, the reason will be explained to you. It is possible that new information may become available while you are in the study. You will be told in a timely manner about any other new information that might affect you and your welfare, and you will be asked whether you wish to continue in the study or not.

TREATMENT AND COMPENSATION FOR INJURY

If you become ill or hurt in the study, you will get appropriate medical care right away. If you have any questions, concerns or complaints about this study or experience any problems, you should contact Dr. Waleed Alhazzani at 905-902-2572 or Dr. Kimberley Lewis at 289-775-7334. By signing this consent form you are in no way waiving your legal rights, or releasing the investigator from their legal and professional responsibilities.

You will not be paid for taking part in this study. All the study procedures will be done at no cost to you, your family or the health system.

RIGHTS AND CONFIDENTIALITY

Your health care will not be influenced by your decision about whether to participate in the study. If you do not participate, you will possibly have a cuff leak test performed once you are ready to breath on your own, prior to removing the breathing machine. Should you agree to join the study now, you may still withdraw at any time, for any reason, and we will continue to give you the best care possible. Information obtained under your original consent up to the point of withdrawal will be retained and used in the analysis, as well as vital status.

Any information learned during the study will be kept confidential. The original medical records and information may be reviewed by the study investigator and/or her representatives and the Hamilton

