UTHealth Houston

Comparison of mechanical ventilation with low and high tidal volumes in acute spinal cord injury: A pilot randomized comparative effectiveness trial

NCT04912583

Version Date: 02/23/2023

CONSENT TO TAKE PART IN RESEARCH

Simple Study Title: Comparison of low and high tidal volumes in acute spinal cord injury

Full Study Title 1: Comparison of mechanical ventilation with low and high tidal volumes in acute spinal cord injury: A pilot randomized comparative effectiveness trial

Study Title 2: "Effects of mechanical ventilation and tidal volumes on inflammatory biomarkers in people with spinal cord injury."

Principal Investigator: Radha Korupolu, MD, MS, Associate Professor, Physical Medicine and Rehabilitation, The University of Texas Health Science Center

Study Contact: Research Assistant: Shrasti Lohiya; [redacted]

This study aims to identify optimal ventilator settings in people with spinal cord injury (SCI) who require mechanical ventilation to identify optimal settings to decrease ventilated related complications. We are comparing two different tidal volume settings currently used in routine clinical practice for people with SCI. Tidal volume is the amount of air that moves in or out of the lungs with each breath (inspiration or expiration). In people who receive mechanical ventilation this amount can be controlled by your physician. Mechanical ventilation with proposed tidal volume ranges in our study are current standard of care for your condition. If you choose to participate in this study, you will be asked to provide consent to allow us to randomly assign either a low tidal volume of 8-10 ml/ kg predicted body weight or 14-16 ml/kg predicted body weight randomly. Both groups will receive positive end-expiratory pressure (PEEP: pressure applied to your airway to prevent complete emptying of lungs). We will also collect three blood and tracheal samples during the study period. The total amount of time you will be in this study is from the time of admission to TIRR Memorial Hermann hospital to the time of discharge from TIRR Memorial Hermann hospital.

There are potential risks involved with this study that is described in this document. Some known risks and discomfort of drawing blood include temporary discomfort from the needle stick, the possibility of pain or bruising at the blood draw site. Similarly, tracheal sample collection can also result in temporary discomfort. There may be potential benefits to you, such as the decreased risk of pneumonia.

There are alternatives to participating in this research study, such as not participating. Usual care is not impacted by participating in this study.

Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not affect the clinical care you receive at the University of Texas Health Science Center at Houston (UTHealth Houston Houston), or Memorial Hermann Healthcare System.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?
The purpose of this study is to see how well low versus higher tidal volume settings work at treating people

with spinal cord injury. This study will compare the currently used ventilator settings in people with SCI.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This will not include information that can identify you. After the study has ended, website will include a summary of the results. You can search this website at any time.

Who is being asked to take part in this study?
You are being asked to take part in this research study because you have a spinal cord injury, and you are dependent on mechanical ventilation at the time of admission to TIRR. This study is a multi-site study being conducted by UTHealth Houston Houston at TIRR Memorial Hermann. About 30 people will participate in the study, all of whom will be patients at TIRR Memorial Hermann.

What will happen if I take part in this study?
Being in this study is different than getting regular care from your doctor. With regular care, your doctor decides on the treatment plan. If you join the study, you have a 50/50 chance of being in either group. Since the assignments are random, you might end up with a tidal volume setting that is different from what you and your doctor would have chosen. Before you join the study, please be sure you are okay with being assigned to either of the two study groups.

- If you consent to participate in this study, you will be randomly assigned to receive either low or high tidal volume (amount of air pushed by the ventilator to your lungs) settings along with PEEP (pressure applied to your airways to prevent complete emptying of your lungs).
- You will undergo standard respiratory care and weaning process per standard of care at TIRR.
- We will obtain blood and tracheal aspirate samples three times during your stay at TIRR to check markers of inflammation. We will collect 2-3 ml of blood (which is approximately half teaspoon) three times during your stay at TIRR. The samples collected for biomarkers will not be kept for future research after the end of this study.
- We will collect data on your age, sex, spinal cord injury, current medications, ventilator settings, and any adverse events from electronic medicalrecords.

Currently, It is unknown whether low or high tidal volume will benefit or be associated with less risk of adverse events. For this reason, some study participants must receive lower tidal volume and some higher tidal volume. This will allow a careful comparison to study the benefits and side effects of the two ventilator settings proposed in this study. You will not know if you are receiving lower or higher tidal volume.

For venipunctures for blood samples –
You will have about 2-3 ml of blood drawn from a vein in your arm 3 times over 4 weeks. The total amount of blood withdrawn during your participation will be about 10 ml (about 2 tsp.).

How long will you be in the study?
If you agree to take part, your participation will last for duration of your stay at TIRR Memorial Hermann

Hospital.

What choices do you have other than this study?
You may select other options than being in this research study which include usual care. You are physician may choose a tidal volume which typically falls within the range proposed in this research study (8-16 ml/kg predicted body weight). Your physician may or may not keep you on PEEP (pressure applied to your airways to prevent complete emptying). Tidal volume settings proposed in this study and PEEP are options ifyou

choose as a part of usual care.

What are the risks of taking part in this study?
There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision. If you choose to take part in this study, there is a risk that the lower tidal volume setting may not be as good as a higher tidal volume in treating your condition. You could also have side effects from the mechanical ventilation with proposed tidal volume settings, which is the standard of care for your current condition. These side effects are similar to what you would get with the usual treatment.

Some of the most common side effects that the study doctors know about are:

- Risk of pneumonia
- Risk of lung injury
- Discomfort from mechanical ventilation
- Discomfort from blood draws include pain, bruising
- Discomfort from collection of tracheal aspirates
- There is a risk that confidentiality will be inadvertently compromised.

There may be some risks that the study doctors do not yet know about.

What are the benefits to taking part in this study?
You may not receive any benefit from taking part in this study. It is possible that you will be assigned to a setting that has fewer adverse events or risks. This study may help the study doctors learn things that may help other people in the future.

Can you stop taking part in this study?
You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Radha Korupolu, MD at [redacted]

Your doctor can stop the study at any time. Your doctor may stop your participation in the study if your condition worsens, the study is stopped, you do not meet all the study requirements, or the study is not in your best interest. If your participation in the study is stopped, your doctor will discuss other options for your treatment.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While participating in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

What happens if you are injured during the study?
If you suffer an injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You or your insurance company will be billed for any treatment. You should report any such injury to Radha Korupolu, MD, at [redacted]. You will not give up any of your legal rights by signing this consent form.

What are the costs or compensation of taking part in this study?
There are no financial costs to you for participating in this study. If you receive a bill that you believe is related to your taking part in this research study, please contact Radha Korupolu, MD, at [redacted] with anyquestions.

You will be paid for your time to take part in the study. You will be paid $25 during each sample collection (blood and tracheal aspirate) for the mechanical ventilation group. You will be paid for completing the baseline sample collection ($25 gift card value), the second sample collection ($25 gift card value), on the third sample collection ($25 gift card value). Thus, you can earn up to $75 in gift card value ($25 + $25 + $25 = $75) for participating in the study. You will receive one gift card for the total amount you earned during the course of the study at the end of your participation in the study.

How will privacy and confidentiality be protected?
Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth Houston, or Memorial Hermann Healthcare System to use and disclose (release) your health information. The health information that we may use or disclose for this research includes your medical record such as your demographic information, medical history, pain scores, physical examination results, and treatment results. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

Personal identifiers such as your name and medical record number will be removed from the information and samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

If you are not comfortable with the use of your data or specimens in future research, you may not want to participate in this study.

People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them. You will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify you is removed from

your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Representatives of the organizations listed below will see your name and other personal identifiers when

they review your research records and medical records for the purposes of verifying study data:

- Representatives of UTHealth Houston and/or Memorial Hermann Health System.

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth Houston and Memorial Hermann Health System may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this

Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact Radha Korupolu in writing at TIRR Memorial Hermann, 1333 Moursund street, Houston, 77030.

This Authorization will expire 15 years after the end of the study.

Whom can you contact if you have questions about the study?
If you have questions at any time about this research study, please feel free to contact Shrasti Lohiya at [redacted], as they will be glad to answer your questions. You can contact the study team

to discuss problems, report injuries, voice concerns, and obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at [redacted]

Schedule of events:

Day 0-1	Screen for eligibility and approach for consent
Day 1-2	Obtain consent and randomization
Day 1-2	Baseline blood and tracheal specimen for inflammatory marker analysis
Day 1-4	Titrate tidal volume to achieve respective targets in each group
Day 4-6	2nd blood and tracheal specimen (48 hrs after achieving target Vt)
Days 14-18	3rd sample (postweaning or 2-week sample)
Day 0- Discharge	Adverse event monitoring, demographics and outcome data collection

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date	Time
Printed Name of Legally Authorized Representative	Signature of Legally Authorized Representative	Date	Time
Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date	Time