

THE UNIVERSITY OF TEXAS



Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Ventilatory Strategy to Prevent Atelectasis During Bronchoscopy under General Anesthesia (VESPA Trial)
2019-0387

Subtitle: VESPA Trial

Study Chair: Roberto F. Casal

Participant's Name

Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

STUDY SUMMARY

Atelectasis (partial or complete collapsed lung) is a known side effect that sometimes happens during a bronchoscopy.

The goal of this clinical research study is to compare 2 different types of ventilation in patients who are having a bronchoscopy and will be under general anesthesia to learn if one method results in a lung collapse less often than the other.

In this study, the standard of care ventilation (mechanical ventilation) will be compared to an investigational ventilation (Ventilatory Strategy to Prevent Atelectasis [VESPA]).

This is an investigational study. Mechanical ventilation is considered the standard of care during bronchoscopy. The use of VESPA ventilation is considered investigational.

Future patients may benefit from what is learned. There are no known benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you

may experience low blood pressure or air leak into the tissue surrounding your windpipes or around the lung.

You can read a list of potential side effects below in the Possible Risks section of this consent.

Your active participation in the study will be over after your bronchoscopy. However, the study staff will continue to collect information about your health from your medical record from that point on.

The 2D and 3D fluoroscopy imaging scans and ultrasound imaging (described below) will be provided at no cost to you, because they are being collected for study purposes only. You and/or your insurance provider will be responsible for all other costs related to your bronchoscopy procedure and routine care.

You may choose not to take part in this study.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the doctor decide if you are eligible:

- You will have a physical exam.
- You will have a CT scan of the chest.
- If you can become pregnant, blood (about 1 teaspoon) or urine will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

If you are found to be eligible to take part in this study, at your scheduled pulmonary clinic visit, the study staff will examine you to confirm that you can have a bronchoscopy with biopsies to check the status of the disease. This bronchoscopy with biopsies is considered part of standard care. You will be asked to sign a separate consent form for that procedure that will explain the procedure in more detail, including its risks.

If you agree to take part in this study, you will be randomly assigned (as in the flip of a coin) to 1 of 2 groups. This is done because no one knows if one study group is better, the same, or worse than the other group. You will know which intervention you have been assigned.

- **Group 1 – Control/Standard-Care arm:** If you are assigned to Group 1, the anesthesiologists (doctors who make you fall asleep during the bronchoscopy) will use a standard short breathing tube called a laryngeal mask airway (LMA). They will set the oxygen and air pressure levels of the breathing machine based on standard care procedures.

- **Group 2 – VESPA Treatment arm:** The anesthesiologist will use a longer breathing tube called an endotracheal tube (ETT), so that a higher air-pressure level can be used in your lungs during the bronchoscopy. Also, the level of oxygen given will be monitored so that you do not receive too much, which can result in lung collapse.

Your doctor will use an imaging machine called a fluoroscope to take 2D and 3D-images of your lungs, as well as an ultrasound machine, in order to check for any signs of lung collapse. These images will be collected 2 times: right after the LMA or ETT is placed, and once again within 20-30 minutes after it is placed. It will take about 5-10 minutes to collect all images.

Before leaving, you will have chest x-rays to check your lungs.

As part of the study procedures, researchers will also collect information from your medical record about your medical history and demographic information (such as your age, sex, and race).

During the first 48 hours after the procedure, you will be asked about any side effects you may have had. This may be done at the clinic or by phone. If you are called, the call should take about 5-10 minutes.

Up to 76 participants will be enrolled on this study. All will take part at MD Anderson and its participating Cancer Network site(s).

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

If you are assigned to the **VESPA** group, the intervention may cause an air leak around your windpipe or lungs, low oxygen level during the procedure, and/or low blood pressure.

The fluoroscope used to look for collapsed lungs exposes you to a small amount of radiation (about the same amount of radiation as a chest CT scan).

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Roberto F. Casal, at 713-792-6238) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.
5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.
6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.
8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research

Research samples collected from you as part of this study **may** be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you.

Authorization for Use and Disclosure of Protected Health Information (PHI):

- A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
 - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
 - The IRB and officials of MD Anderson
 - Study monitors and auditors who verify the accuracy of the information
 - Individuals who put all the study information together in report form
 - B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.
 - C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.
- Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.
- D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.
 - E. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

SIGNATURE OF PARTICIPANT

DATE

PRINTED NAME OF PARTICIPANT**LEGALLY AUTHORIZED REPRESENTATIVE (LAR)**

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

SIGNATURE OF LAR

DATE

PRINTED NAME and RELATIONSHIP TO PARTICIPANT**WITNESS TO CONSENT**

I was present during the explanation of the research to be performed under Protocol 2019-0387.

SIGNATURE OF WITNESS TO THE VERBAL CONSENT

DATE

PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR)

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

PRINTED NAME OF WITNESS TO THE VERBAL CONSENT**PERSON OBTAINING CONSENT**

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

PERSON OBTAINING CONSENT

DATE

PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

NAME OF TRANSLATOR

SIGNATURE OF TRANSLATOR

DATE

Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

DATE

PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION