Randomized Trial of Sedative Choice for Intubation (RSI)

NCT05277896

Informed Consent Form Version Date: August 16, 2023

Institutional Review Board
Informed Consent Document for Research
MASTER CONSENT

Study Title: Randomized Trial of Sedative Choice for Intubation ("RSI")
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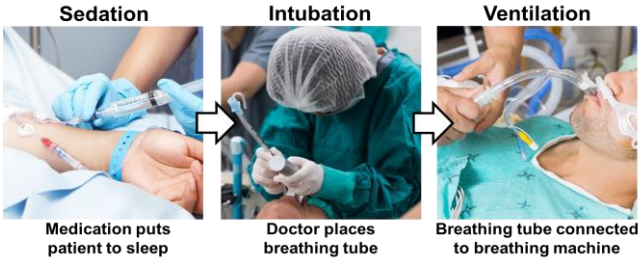
Part 1 of 2: MASTER CONSENT

Name of participant: _____ Age: _____

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:



For a sick patient to receive support with a breathing machine, a breathing tube must be placed through the mouth and into the windpipe. The goal of this study is to improve the safety of this brief 2-minute procedure, during which serious problems may occur with low oxygen levels, low blood pressure, or sudden stopping of the heart. The first step of the procedure is giving a medication to make you sleepy and relaxed. The most commonly used medications for this purpose are ketamine and etomidate. Currently some patients receive ketamine and some receive etomidate, and it is unknown whether one is better. To understand whether ketamine or etomidate is a better medication for placing a breathing tube in the windpipe, doctors and nurses in this unit are comparing the two medications. When doctors feel that either ketamine or etomidate are safe options for a patient but are unsure which is best, they allow the study to choose between the two medications.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because your doctors feel your medical condition requires the placement of a breathing tube, and your doctors feel that both ketamine and etomidate are

safe options for you – but they do not know whether one medication would be better for you than the other.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Possible Risks of Ketamine:
When ketamine is used to make patients sleepy for the placement of a breathing tube, the most common side effects are:

- Confusion, hallucinations, and irrational behavior (>10%)

Uncommon but more severe potential side effects of ketamine include:

- Low or high blood pressure, low or high heart rate, cardiac arrest, severely slowed breathing, allergic reactions including anaphylaxis, increased intracranial pressure (high pressure in the brain), loss of appetite, nausea and vomiting, spasm of the vocal cords, or double vision

Possible Risks of Etomidate:
When etomidate is used to make patients sleepy for the placement of a breathing tube, the most common side effects are:

- Myoclonus (a sudden spasm of the muscles) or other transient muscle movements (33%), suppression of the adrenal gland (>10%), nausea and vomiting (>10%), hiccups (<10%)

Uncommon but more severe potential side effects of etomidate include:

- Low or high blood pressure, low or high heart rate, cardiac arrest, severely slowed breathing, allergic reactions including anaphylaxis, spasm of the vocal cords

Risks of breathing tube placement using ketamine or etomidate:
Both ketamine and etomidate have been approved by the Food and Drug Administration (FDA) for use during the placement of a breathing tube. Both are commonly used in routine medical care (without participation in a research study). It is unknown whether using ketamine or etomidate during the placement of a breathing tube affects the risk of serious problems with low oxygen levels, low blood pressure, cardiac arrest, brain injury, or death.

Risks of participation in the study:
Because you will be receiving a breathing tube as part of your clinical care (even if not participating in a research study) and your doctors feel that both ketamine and etomidate are safe options for you – but are uncertain which is better, participating in this study is not expected to add significant risk compared to your routine medical care (without participation in a study). The study does use information from your medical record to help understand the effects of each medication.

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Good effects that might result from this study:
You may have personally benefitted if the medication used during your breathing tube placement is ultimately found to be best. Your participation will help doctors and nurses everywhere better understand the safest approach to breathing tube placement for future patients like you.

Procedures to be followed:
Because your doctors feel that both ketamine and etomidate are safe options for you but are uncertain which is better, the choice between them is made by the study in a way that will help your doctors understand which medication is best ("randomization"). During placement of the breathing tube, a doctor or nurse will record your heart rate, blood pressure, oxygen level, and receipt of medications. The study affects only the choice to use ketamine or etomidate. Every other aspect of your care will be determined by you and your doctors and nurses. After your breathing tube is placed, the only study procedure will be the collection of details of your hospital stay from your medical record.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way. If you decide to stop being part of this study, we will not collect any additional information from your electronic medical record (the only remaining part of the study). We will, however, keep the data already collected and review publicly available vital statistics records to be able to report on the safety of the study.

Clinical Trials Registry:
A description of this clinical trial will is available on ClinicalTrials.gov at https://classic.clinicaltrials.gov/ct2/show/NCT05277896, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Privacy:
Information about you collected as a part of this study will be available to the doctors and researchers leading this study and may also be made available to others to use for future research. This will help researchers answer additional important questions about the causes, risks, treatments, or how to prevent this and other health problems. To protect your privacy, we will not release publicly your name, birth date, or any other identifying information.

Study Results:
The results of this study will be made public once the study is completed using methods such as press releases, social media advertisements, and advertisements in local newspapers.

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STUDY SITE INFORMATION

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Part 2 of 2: STUDY SITE INFORMATION

Site Name:	Vanderbilt University Medical Center
Site Principal Investigator:	Dr. Jonathan Casey
Site Principal Investigator Contact:	615-208-6139

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Payments for your time spent taking part in this study or expenses:
You will not receive payment for your participation in this study.

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator with input from the National Institute of Health or the Patient-Centered Outcomes Research Institute that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt, the National Institute of Health, or the Patient-Centered Outcomes Research Institute to pay for the costs of any additional care. There are no plans for Vanderbilt, the National Institute of Health, or the Patient-Centered Outcomes Research Institute to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Jonathan Casey at (615) 208-6139. If you cannot reach the research staff, please page the study doctor at (615) 835-5496.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Medical Center Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

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Confidentiality:
Information obtained about you for this study will be kept confidential to the extent allowed by law. Research information that identifies you may be shared with the Institutional Review Board (IRB), the Food and Drug Administration (FDA), and the Office for Human Research Protections (OHRP). There is a risk that if people outside the study get your health data, they could misuse it for purposes other than those outlined in this notification form. The study team has strict privacy and confidentiality protection procedures in place to prevent this from occurring so the chance of this happening to you is extremely small.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Authorization to Use/Disclose Protected Health Information
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

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Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____

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STATEMENT BY PERSON AGREEING ON BEHALF OF THE PATIENT TO BE IN THIS STUDY

I, _____ [name of decision-maker/surrogate], am the _____ [state relationship to participant] of _____ _____ [state participant's name]. I have read the informed consent document or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that an investigational treatment may be administered to _____ [participant's name]. I believe receiving such treatment would be in the interests of _____ [participant's name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation and he/she will receive alternative treatments without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend's participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent. If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

_____ ___/___/___
Signature of Health Care Decision-Maker/Surrogate Date

_____ ___/___/___
Signature of Witness Date

_____ ___/___/___
Name and Signature of person obtaining consent Date