Use of Sugammadex for Reversal of Paralysis in Microlaryngoscopy

NCT03111121

01Sep2016

More than Minimal Risk
Consent and HIPAA Form

Principal Investigator	Pavithra Ranganathan, MD
Department	Anesthesiology
Study Title	Use of Sugammadex for Reversal of Paral1,1sis in Micro laryngoscopy
Co-lnvestigator(s)	Kathrine Allen MD; Matthew Ellison MD; Tanya Fancy MD; Jason Paul Mcchesney MD; Hassan H. Ramadan MD; Rusha Patel MD; Jason L. Shepherd MD; Walter Kielkowski CRNA; J. Sean Morris CRNA; Kelly Myers CRNA; Michael I<. Ritchie, MD; Payam Heiraty, MD; Jeffson Chung MD; Kristin Dragan, MD and D. Chad Sizemore, MD
Sponsor	Investigator initiated: Merck Investigator Studies Program (MISP)
Contact Person:	Pavithra Ranganathan, MD 1 Medical Center Drive Department of Anesthesiology P. 0. Box 8255 Morgantown, WV 26506

This is not a consent form for surgery or anesthesia. Your surgeon and/or anesthesiologist will provide a separateconsent form for those procedures.

In the event you experience any side effects or injury related to this research, you should contact Dr. Ranganathan or Dr. Ellison at (304) 598-4929. (After hours contact: Anesthesia at (304) 598-4000 ext. 76263. If you have any questions, concerns, or complaints about this research, you can contact Dr. Ranganathan at (304)598-4929.

For information regarding your rights as a research subject, to discuss problems, concerns, or suggestions related to theresearch, to obtain information or offer input about the research, contact the Office of Research Compliance at (304) 293-7073.

In addition, if you would like to discuss problems, concerns, have suggestions related to research, or would like to offerinput about the research, contact the Office of Research Integrity and Compliance at 304-293-7073.

'

1;

Introduction

You,_____, have been asked to participate in this research study, which has been explained to you by _____. This study is being conducted by Dr. Ranganathan Department of Anesthesiology at West Virginia University with funding support and Sugammadex (Bridion®) provided by Merck Investigator Studies Program.

Purpose(s) of the Study

The main purpose for this study is to collect data on the use of muscle relaxants and 2 types of Food And Drug Administration (FDA) approved reversal agents (1- Neostigmine, 2- Sugammadex) to see if Sugammadex will reduce thetime to removal of breathing tube after the end of surgical procedures with micro laryngoscopy (examination of the airway, interior of the larynx with a laryngoscope with binocular magnification) as explained to you by your surgeon.

Researchers will collect data on the time when the surgeons are done with the procedure to the time the breathing tube is removed from the airway. The surgeons' reports as optimal surgical conditions for ease looking at your airway, changes in vital signs if there is any from your baseline vital signs, amount of anesthetics used, total amount narcotics needed intra-operatively and post operatively, the total Operating Room time, PACU time and adverse events.

WVU expects to enroll approximately 84 completed subjects. WVU is the only site.

Description of Procedures

This study involves collecting data on subjects that are going to have a procedure that require intubation andexamination of airway and related airway structures.

You are eligible to participate in this study since you are going to have a procedure to look at your throat, vocal cords and voice box structures. You are also eligible because you are 18 years of age or older and don't have an allergy to any of the medications that we may use as part of your anesthetic.

Screening phase: You will discuss this consent with the research staff in the clinic or surgery suite. You may take a copy of this form home to read and make a decision prior to your procedure date.

Participation is voluntary and if you decide to participate please inform the staff who will go through the consentprocess with you.

Treatment phase: Surgery

You will have your surgery as your surgeon requires and you will be randomized (like flipping a coin) into 1 of 2 groups:Both groups will receive standard of care treatments. The research team will collect data on the groups. You will be given a unique study ID number, i.e. 0001-ABC, to help keep your identification confidential. The principal investigatorand study coordinator will have access to the master code that links you to the research code. It will be on a computer
and is password protected.

Both groups will receive a standard general anesthetic. Both groups will receive all other standard medications given aspart of a general anesthetic.

Group 1 will receive reversal of paralysis with a medication called

neostigmine. Group 2 will receive Reversal of paralysis with a medication

called Sugammadex.

Follow-up:

Post anesthesia care unit (PACU):
The nursing staff will document when you are ready for discharge from this area. These nurses will not know what groupyou are in. That information will be kept confidential and coded.

You may receive a phone call within 30 days if you have had an adverse event such as low blood pressure, palpitations, shortness of breath, low oxygen levels after procedure, or needed to be re-intubated (replace tube in throat to help youbreath). If you have not had an adverse event you will be finished with the study after discharge from the post anesthesia care unit.

Your participation may be terminated by the investigator without regard to your consent at any time if the investigator feels it is necessary.

Risks and Discomforts

Drugs often have side effects. The drugs used in this program may cause all, some, or none of the side effects listed. In addition, there is always the risk of uncommon or previously unknown side effects. There may be reasonably foreseeable invasive or non-invasive risks or discomforts due to your surgery. You will discuss and sign a surgery consent with your surgeon.

Neostigmine Side effects
Serious side effects may include: muscle weakness, slurred speech, vision problems, feeling like you might pass out,severe stomach cramps or diarrhea, trouble breathing, cough with mucus, fast or slow heart rate, convulsions,

Less serious side effects may include: headache, drowsiness, mild nausea, vomiting, gas, urinating more than usual, cold sweat, warmth or tingly feeling, mild rash or itching.

Sugammadex Side effects
Most common side effects seen in >10% of subjects are vomiting, pain, nausea, and head ache.
Some serious side effects may include slow heart rate, low blood pressure and allergy to the medication.

This study may involve risks to the unborn child. For this reason, women who are pregnant will not be accepted.
You must use a medically approved method of birth control while you are on this study and 7 days after receiving Sugammadex.

Men who are able to father a child should never have unprotected sex with a woman while in this study because it is not known if the drug is present in semen or sperm.

Alternatives

You do not have to participate in this study.

Benefits

You may not receive any direct benefit from this study. The knowledge gained from this study may eventually benefit others.

Financial Considerations

Sugammadex will be provided by Merck Investigator Studies Program at no cost to you, if you receive it.
There are no special fees for participating in this study, but any expense associated with current therapy or treatment of side effects will be billed to you or to your insurance company.

Voluntary Compensation

If you are injured as a result of this research, treatment will be available. Responsibility for this treatment will be borne by you or your insurance company. In the event that you are physically injured as a result of participating in this research, care will be available. You will, however, be responsible for the charges for the care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Ranganathan at 304-598-4929 if you are injured or for further information.

Confidentiality

Any information about you that is obtained as a result of your pa1iicipation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or

may be inspected by the study sponsor or federal regulatory aut11oriiies (including the FDA if applicable) without your additional consent.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US 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.

HIPAA

We know that information about you and your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others for research purposes.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Patient/West Virginia University Hospitals

Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliated, WVU, WVU Hospitals. It also includes each site's research staff and medical staff
- Health care providers who provide services to you as part of this research study.
- The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law.
- Merck and the people and companies that they use to oversee, manage, or conduct the research.
- The members and staff of any Institutional Review Board (IRB) that oversees this research study.
- West Virginia University Office of Research Compliance and Office of Sponsored Programs.

The Following Information Will Be Used

Information from your existing medical records and new information about you that is created or collected during the study such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, El<G results, demographic data, pulmonary tests, imaging scans and study forms.

The Information is Being Disclosed for the Following Reasons

- o Review of your data for quality assurance purposes
- c Publication of study results (without identifying you)

You May Cancel this Authorization at Any Time by Writing to the Principal Investigator

Pavithra Ranganathan, MD at 1 Medical Center Drive Department of Anesthesiology P. 0. Box 8255 Morgantown, WV
26506

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re disclose it and then the information mayno longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time.

Refusal to participate or withdrawal will not affect your care and will involve no penalty to you. Refusal to participate or withdrawal will not affect your future care, or your employee status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, thisinformation will be given to you so that you can make an informed decision about whether or not to continue your participation.

You have been giv n the opportunity to ask questions about the research, and you have received answersconcerning areas you did not understand.

Upon signing this form, you will receive a copy.

I willingly consent to participate in this research.

v

Signatures

Signature of Subject, _____

Date Time

Printed Name _____

The participant has had the opportunity to have questions addressed. The participant willinglyagrees to be in the study.

Signature of Investigator or Co-Investigator

_____

Date Time

Printed Name _____