Study Title: Best Practice With Rocuronium, Neostigmine, Sugammadex, and Subjective Monitoring

NCT03543826

Document title: Informed Consent

Date of the document: 5/8/2019

UNIVERSITY OF WASHINGTON
CONSENT FORM

Best Management of Muscle Relaxation with Rocuronium Using Objective Monitoring and Reversal with Neostigmine or Sugammadex

Researcher:

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Other contact: _____

24-hour emergency contact number: 206-744-3000. Call the hospital operator and ask to page the on-call anesthesiologist

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Patients who have surgery and receive general anesthesia often receive muscle relaxants (called neuromuscular blocking drugs or NMBDs). These muscle relaxants allow an anesthesiologist to perform tracheal intubation (placement of a breathing tube in the windpipe) and help with surgery. After surgery, an anesthesiologist monitors how the muscle relaxants wear off, and gives a drug to help reverse the effect of the muscle relaxants before the tracheal breathing tube is removed and you are awakened and taken to the postoperative care area (PACU).

A patient who receives muscle relaxants for their routine care can experience a leftover effect of the drug after their general anesthesia wears off.

At HMC and UWMC, the management of muscle relaxants in patients used for routine care varies provider by provider. The different ways to manage muscle relaxants are all within the scope of standard clinical care that a patient may experience for his/her surgery. Researchers at HMC are doing a study to see if using a specific plan to manage muscle relaxants will help decrease the risk of muscle weakness after general anesthesia.

STUDY PROCEDURES

We are asking you to be in this study because you are scheduled to have a surgery where you will undergo general anesthesia and receive a muscle relaxant (NMBDs) for your clinical care. If you agree to be in this study, we will require your anesthesiologist to follow a specific plan for managing muscle relaxants given to you for your surgery. Study staff and your provider will also

use objective nerve stimulators to monitor your care. This specific plan may be used normally for routine care at the discretion of your anesthesiologist. The difference is that if you participate in this study, only this plan for the management of muscle relaxants will be followed for research purposes instead of a plan decided at the discretion of your anesthesiologist. The following plan will take place for this research study:

Before Surgery
After you are given general anesthesia for your routine care, a member of the study team will perform baseline clinical care monitoring by using either the TwitchView Monitor or the Stimpod 450 tool. These tools are a type of nerve stimulator that may sometimes be used in routine care. The Stimpod and TwitchView tools deliver a small amount of electricity to your ulnar nerve at the wrist and causes a twitch response in the thumb. These tools measure this twitch response with greater precision than what is possible if your anesthesia provider isjudging the twitch response by visual or manual assessment which is an alternative method during routine anesthesia care. We will make use of one of these tools for this study and will record information for the study.
The dose of the muscle relaxant (NMBD) you receive for routine care will be calculated based on your specific height and gender.
During Surgery
We will observe how well the muscle relaxant is working.
When extra muscle relaxant is needed for your routine care during surgery, it will be given to you based on this monitoring and your specific height and gender.
If it is clinically appropriate, your provider will avoid giving extra muscle relaxant during the last 30 minutes of the surgery
After Surgery
After your surgery is over, you will receive a drug for routine care that will help reverse the effects of the muscle relaxation.
Depending on the reversal drug you receive for routine care, the dose you will receive will be calculated based on your height or your total body weight.
Depending on the reversal drug you receive for routine care, your provider may wait at least 3 or 10 minutes for the reversal drug to set in before the endotracheal tube is removed from your windpipe (this removal is called extubation).
At the time of removal of your breathing tube (extubation), the study team will measure the amount of muscle relaxation that may be remaining. We will use either the TwitchView Monitor or the Stimpod 450 tool and record the results for this study. If we are unable to obtain this measurement at the time of extubation, we will try to do this when you arrive in the PACU.
We will record information from your medical record about your health history and your care before, during and after surgery for the research study. For instance, we will collect information about medications used during surgery information, and characteristics about you as a patient (age, height, BMI, etc.).

Because the research will take place around the time of your surgery when you are feeling the effects of general anesthesia, you may not have any memory of the research procedures and no follow-up care is required.

RISKS, STRESS, OR DISCOMFORT

The different ways to manage muscle relaxants in surgical patients are all within routine clinical care. If you choose to participate, you may receive similar care for the management of your muscle relaxants.

You will not experience discomfort from the nerve stimulation performed while you are under general anesthesia. If we conduct this monitoring in the PACU, you may feel some discomfort as you are recovering from surgery. You may experience mild to moderate discomfort from the nerve stimulation. The nerve stimulator delivers a small amount of electricity to your wrist and because you are awake you may feel these impulses. Patients who have participated in similar studies at other hospitals have tolerated this well and have not reported much pain. Many patients do not remember this experience after leaving the recovery room. In the unlikely event that you tell us the pain is too uncomfortable, we will immediately stop the procedure until the pain resolves and may withdraw you from the study if you find the procedure intolerable. Some people feel that research is an invasion of privacy and have concerns about the privacy of information collected about them. We address these concerns in the Confidentiality of Research Information section below.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You do not have to be in this research study. If you decide not to participate in this study, the decisions about muscle relaxant management will be decided by the anesthesia team and not by the research team.

BENEFITS OF THE STUDY

You may not directly benefit from this study.

You may benefit from additional monitoring of the neuromuscular function from this study. If we detect significant leftover effect of the muscle relaxing drugs, then your anesthesiologist will monitor you more closely after surgery.

We hope that results of this study can help future patients by making monitoring in the operating room more effective and by guiding the best possible management of muscle relaxants.

CONFIDENTIALITY OF RESEARCH INFORMATION

Information about you will be confidential. However, if we learn that you have residual paralysis in the recovery room, we will let your anesthesiologist know so that he/she can more closely monitor you.

Your name and other personal information will be linked to a unique study ID. Your study ID will not include any information that can identify you. All data we collect from you will be

coded with your study ID and stored in a secure place or on a password protected computer database. The master list linking your identifying information to your study data will be kept in a separate, secure place. The link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law.

If we publish the results of this study, we will not use your name or other personal information.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

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.

OTHER INFORMATION

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

You will not be charged for study-related procedures. You or your insurer will be responsible for costs related to standard clinical care. You will not be paid for taking part in this study.

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

RESEARCH-RELATED INJURY

If you think you have a medical problem or illness related to this research, contact Stephan Thilen at the contact information above. He will treat you or refer you for treatment.

If you are injured as result of being in this study, necessary medical treatment will be offered at a UW Medicine facility. The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. You may also call collect to the UW Human Subjects Division at 206-221-5940 if you do not otherwise have access to a telephone. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any

right to seek payment by signing this consent form. We will bill your health insurance for treating problems that result from your surgery or underlying condition or from standard clinical care. If you have no health insurance or your insurance refuses to pay, we will bill you.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject