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Quality of Recovery after Reversal with Neostigmine or Sugammadex
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RESEARCH CONSENT FORM

Project Title: Pulmonary function, muscle strength, time to extubation, and quality of recovery in the post anesthesia care unit after reversal of neuromuscular blockade with neostigmine or sugammadex

Principal Investigator: Ramon Abola, MD
Co-Investigators: Elliott Bennett-Guerrero, MD
TJ Gan, MD
Jamie Romeiser, MPH

Department: Anesthesiology

You are being asked to be a volunteer in a research study.

You are encouraged to take your time in making your decision. You may want to discuss this study with your friends and family.

PURPOSE

The purpose of this study is to determine how recovery after anesthesia is different in patients who receive neostigmine or sugammadex. Neostigmine and sugammadex are both FDA-approved medications to reverse the effect of neuromuscular blockade (paralysis) at the end of surgery. We will be assessing breathing function, hand grip strength, ability to sit independently, and time spent in the post anesthesia care unit before discharge.

Neuromuscular blockade is a routine component of general anesthesia that allows for placement of a breathing tube and optimizing operating conditions. Neostigmine and sugammadex are both FDA-approved medications that reverse neuromuscular blockade at the end of surgery. Residual muscle weakness after anesthesia can result in breathing difficulties, patient discomfort, and poor recovery after surgery.

The “reversal” drug sugammadex is widely used in Europe and elsewhere. It was recently approved by the FDA so there is less experience with its use in the US. We have been using Sugammadex at Stony Brook for several months with good results. Studies have suggested that sugammadex may be a more effective reversal agent compared to our traditional reversal agent, neostigmine. The purpose of this study is to assess differences between the two reversal agents on the quality of recovery after anesthesia.

Any patient who will receive neuromuscular blocking drugs as a component of their anesthesia with reversal of these drugs, at the end of surgery, is eligible for this study. We expect to enroll 80 patients in this study.

PROCEDURES

If you decide to be in this study, your part will involve:

Medical history survey: This survey will ask you questions about your general health during the time of the survey, before your surgery.

Randomization: You will be randomly (by chance) assigned to one of two groups: one group will receive neostigmine with glycopyrrolate for reversal from anesthesia and the other group will receive sugammadex for reversal from anesthesia. Pain management standards will remain unchanged and drugs to prevent nausea and vomiting will be the same in both groups.

Anesthesia: Your anesthesiologist will administer general anesthesia on the day of surgery. As part of this study, you will receive rocuronium, a neuromuscular blocking drug which is a routine medication given during general anesthesia. The anesthesiologist will maintain a specific depth of neuromuscular blockade that will also provide optimal operating conditions. This neuromuscular blockade will be reversed at the end of surgery. Either neostigmine or sugammadex will be given for reversal of neuromuscular blockade depending on which group you have been assigned to. The administration of opiate medication (fentanyl) and benzodiazepine medication (midazolam) as part of your anesthetic care will be standardized to typical amounts.

Postoperative Assessment: Measurements will be taken at 30, 60 and 120 minutes after surgery, in the post anesthesia care unit (PACU), to assess breathing function and hand grip strength. Breathing function will be measured using an incentive spirometer. An incentive spirometer is a device that measures how deeply you can breathe in. If you are ready for discharge from the PACU prior to 2 hours after surgery, you will remain long enough to complete the 2-hour assessment.

Quality of Recovery: We will ask you to take a 15 question survey called Quality of Recovery (QOR) 24 hours after surgery. This asks you questions about your well-being, pain, nausea, anxiety, sleep and other questions. You will complete a QOR15 survey either in person (if still hospitalized) or via telephone with a research coordinator/assistant.

The duration for participation in this study is 2 days (from the day of your surgery through approximately 24 hours after you are discharged from the recovery room).

RISKS / DISCOMFORTS

Although this study will not involve many changes to the care that you would already be receiving, the following risks/discomforts may occur as a result of being in this study:

Discomfort from the Intravenous (IV) line: In many surgeries as part of your routine (non-study) care, your anesthesiologist will insert a second IV, often after you have been put to sleep for the operation. If a second IV is not inserted as part of your routine care we will place this second as part of the study after you have gone to sleep, since we need a second IV for the study. Some potential risks associated with IV lines include:

- Bleeding/bruising: There is a risk of bleeding at the skin puncture site. There is also the possibility of bruising where the IV is inserted. We will applying pressure directly to the puncture site to minimize the risk.

- Local infection: As with all needle punctures, there is a possibility of local infection. This will be reduced by using antiseptics and by using sterile equipment.

Loss of Confidentiality: Research often poses the risk of loss of confidentiality to subjects who participate. Many persons who would not otherwise be privy to identifiable, private information about the subject may be involved in the research process. To minimize this risk, all the study data that we get from you will be coded and kept locked up. If any papers and talks are given about this research, your name will not be used (see below on confidentiality).

Discomfort from the Train of Four (TOF) monitor: To assess the level of muscle strength, a monitor will be placed on one of your hands during surgery to stimulate the muscles of that hand. This monitor, called a TOF watch, will be used specifically for this research. You may have some muscle soreness from the repeated twitches, though this would be a highly unlikely, unexpected and rare occurrence with this monitor.

Residual muscle weakness: After the surgery has ended and the breathing tube has been removed from your mouth, there is a small chance you may still feel muscle weakness. This is not commonly seen with the drugs we are using for your surgery. However, to minimize this risk further, we will ensure that your muscle strength has fully recovered prior to waking you up, that your lungs are properly breathing on their own without the assistance of any mechanical device such as a ventilator, and that your vital signs are stable prior to waking you up and removing the breathing tube.

Since this is a research study, not all risks may be known at this time; there may be unforeseen risks associated with study participation.

BENEFITS

There is no direct benefit expected as a result of you being in this study

PAYMENT TO THE INSTITUTION

This project is funded, in part, by a grant or contract from Merck Investigator's Program (MISP) to the Research Foundation of Stony Brook University, in support of the Investigators' work on this study

CONFIDENTIALITY

We will take steps to help make sure that all the information we get about you is kept confidential. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used.

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will share the data we get from you in this study with the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable Institutional officials, and certain federal offices, including the Office for Human Research Protections (OHRP), and, where applicable, the Food and Drug Administration (FDA).

Merck, who is providing the grant for this study, will be provided a final study report with descriptive data, tables, data listings and adverse experiences. Any subject level data shared with Merck will be coded with a number and no other personal identifiers such as birth date or study subject initials.

However, if you tell us you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this.

In a lawsuit, a judge can make us give him the information we collected about you.

While you are in this study we will get data about your health from your medical record. We will also get health data from the results of the tests you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the people referenced above (the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and federal offices such as OHRP, FDA) as well as your medical doctor.

Your health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission.

You have the right to stop allowing us to use or give out your health data. You can do this at any time by writing to Ramon Abola. If you do this, we will stop collecting any new health data from you, except if we need to keep an eye on a bad side effect you were having in the study. We will use any data we collected before you wrote your letter. When you sign the consent form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of your health data as described above.
- You have received a form from the University Hospital. It is called the Notice of Privacy Practices form.

Clinical Trial Registry

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".

COSTS TO YOU

There are no foreseeable costs to you.

ALTERNATIVES

Your alternative to being in this study is to simply not participate.

IN CASE OF INJURY

If you are injured as a result of being in this study, please contact the study's principal investigator, Dr. Ramon Abola at telephone # 631-624-7045. The services of Stony Brook University Hospital will be open to you in case of such injury. However, you and/or your insurance company will be responsible for payment of any resulting treatment and/or hospital stay.

YOUR RIGHTS AS A RESEARCH SUBJECT

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will get a signed and dated copy of this consent form to keep.
- You do not lose any of your legal rights by signing this consent form.

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

- If you have any questions, concerns, or complaints about the study, you may contact Dr. Ramon Abola, at telephone # 631-624-7045.
- If you have any questions about your rights as a research subject or if you would like to obtain information or offer input, you may contact Ms. Judy Matuk, Committee on Research Involving Human Subjects, (631) 632-9036, OR by e-mail, judy.matuk@stonybrook.edu.
- Visit Stony Brook University's Community Outreach page, http://www.stonybrook.edu/research/orc/community.shtml for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

Subject Name (print)	Subject Signature	Date

Name of Person Obtaining Consent (print)	Signature of Person Obtaining Consent	Date