Informed Consent Form

TITLE: The use of sugammadex as rescue therapy following inadequate reversal with neostigmine

NCT NUMBER: NCT05661409

IRB APPROVAL DATE: October 4, 2023

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 120 people who are being studied, at Grady.

Why is this study being done?

This study is being done to answer the question: can a lower dose of the drug "sugammadex" be just as effective as a standard dose to reverse the effects of muscle paralysis used during anesthesia. You are being asked to be in this research study because you are scheduled to undergo a surgery that would require muscle paralysis under general anesthesia.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate for one day. The researchers will ask you to do the following: agree to randomly receive a study drug and undergo monitoring of your muscle strength during surgery and in the recovery unit. Some of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts you should know about before deciding?

The study will take time. The drug that is being tested may not work any better than regular care and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- Nausea and/or vomiting,
- Decrease in blood pressure,
- Increase or decrease in heart rate,
- Drug reaction,
- Loss of privacy,
- Breach of confidentiality.

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study

If you choose not to join this study, you will get the normal dose of drugs used to reverse the effects of muscle paralysis used during anesthesia.

Costs

The study sponsor will pay for certain items and services that you may receive if you take part in this study. You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care.

There is more information in the "Costs" section further below.

What Should You Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: The use of sugammadex as rescue therapy following inadequate reversal with neostigmine

IRB #: STUDY00004369

Principal Investigator:
Rebecca Yuen Shi Wong, MBBS MPH
Assistant Professor, Department of Anesthesiology, Emory University

Faculty Advisor: N/A

Sponsor: N/A

Investigator-Sponsor: N/A

Study-Supporter: Georgia CTSA (Clinical & Translational Science Alliance)

Introduction
You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:
- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

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.

What is the purpose of this study?
Patients undergoing surgery may receive an anesthetic medication that would cause muscle paralysis, one of which is “rocuronium”, as well as an anesthetic medication that would reverse the effects of the muscle paralysis after surgery is completed, either “neostigmine” and/or “sugammadex”. These three drugs are FDA approved and are routinely used in the administration of general anesthesia. The lowest dose of “sugammadex” that is FDA approved is 2 mg/kg. The purpose of this study is to determine if a lower dose of “sugammadex” would be just as effective, and we will be studying four doses, i.e. 1 mg/kg, 0.5 mg/kg, 0.25 mg/kg and 0.125 mg/kg.

You are being invited to participate in this study because you are scheduled to undergo a surgery that would require muscle paralysis under general anesthesia. We plan to enroll 120 subjects in this study over a period of one year.

What will you be asked to do?

The duration of the study for you would start from the time that your surgery begins till the time that you leave the post anesthesia care unit, which is usually less than an hour after your surgery ends.

You will receive the standard doses of "rocuronium" for muscle paralysis as well as "neostigmine" for the reversal of the muscle paralysis. If you are still weak after that, you will randomly receive a study drug:

- 2 mg/kg of "sugammadex",
- 1 mg/kg of "sugammadex",
- 0.5 mg/kg of "sugammadex",
- 0.25 mg/kg of "sugammadex",
- 0.125 mg/kg of "sugammadex", or
- Normal saline (placebo)

Random means that you will receive any of these six drugs by chance, similar to rolling dice.

After that, we will measure the time that is needed for you to achieve full recovery of your muscle function. If you are still weak after this, we will give you more "sugammadex" until you achieve full recovery of your muscle function.

How will your study drug be provided?

The study drug that you will be given will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the study drug to you. If you have questions about the study drug, you should ask the principal investigator.

Note: The research team for this study includes non-licensed team members who may obtain your consent, or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example, detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions.

Who owns your study data?

If you join this study, you will be donating your data. If you leave the study, the data that were already collected may still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study drug or procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

- Nausea (23-26%)
- Vomiting (11-15%)
- Pain (36-52%)
- Prolonged intubation: it may take longer than expected to safely remove your breathing tube at the end of the case if there is residual weakness.

The less common risks and discomforts expected in this study are:

- Low blood pressure (4-13%)
- High heart rate (2-5%)
- Low heart rate (1-5%)

Rare but possible risks include:

- Anaphylaxis, which is a severe allergic reaction to the drug (0.3%)

Please note that all these risks and discomforts are also side effects of surgery and general anesthesia as a whole.

If it is biologically possible for you to become pregnant: to protect against possible side effects of the study drug, people who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a person of childbearing ability, you and the study doctor must agree on a non-hormonal method of birth control to use for the next 7 days following your surgery. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant people will be taken out of the study.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?

You may or may not benefit from joining the study. This study is designed specifically to learn more about one of the best ways to reverse the effects of muscle paralysis after general anesthesia. Thus, the study results may be used to help others in the future, including yourself.

Will you be paid for your time and effort?

You will not be compensated for being in this study.

What are your other options?

If you choose not to join this study, you can get care outside of this study. For example, if you remained weak at the end of surgery, you will receive the full dose of “sugammadex” at 2 mg/kg and be monitored until you achieve full recovery of muscle function. The study doctor will discuss these with you. You do not have to be in this study to be treated for your condition.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory/Grady or elsewhere. We may share the data, linked by the study code, with other researchers at Emory/Grady, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory/Grady. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

We will use your data only for research. We will not sell them. Research data and records will be kept for at least 6 years following the completion of the study.

Medical Record

If you have been a Grady patient before, then you already have a Grady medical record. If you have never been a Grady patient, you do not have one. A Grady medical record will be made for you if a Grady provider or facility gives you any services or procedures for this study. Copies of the consent form that you sign will be put in any Grady medical record you have now or any time during the study.

Grady may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Grady medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Rebecca Wong at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Grady will help you to get medical treatment. Neither Grady nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

For Grady, the only exception is if it is proven that your injury or illness is directly caused by the negligence of a Grady employee. “Negligence” is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

The study sponsor will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Grady will submit claims to your insurance for items and services that the sponsor does not cover. Grady will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Grady and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Grady will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

These are some reasons why the researchers may take you out of the study:

- If you did not require general anesthesia or muscle paralysis for your surgery,
- If you did not receive "neostigmine" to reverse the effects of the muscle paralysis, and/or
- If you did not remain weak after "neostigmine" has been given.

Authorization to Use and Disclose Protected Health Information

The privacy and confidentiality of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The Principal Investigator and the research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.

Georgia CTSA (Clinical & Translational Science Alliance) is the Study-Supporter of this study. It may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. It may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

The following people and groups will use and disclose your PHI in connection with the research study to make sure it is done correctly and safely:

- Emory and Grady offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory and Grady IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
- Other researchers and centers that are a part of this study.
- Government agencies that regulate the research, including the U.S. Food and Drug Administration (FDA).
- Public health agencies.
- Research monitors and reviewers.
- Accreditation agencies.

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at Dr Rebecca Wong at [redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. If it is necessary for your health care, your health information will be provided to your doctor. We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Dr Rebecca Wong at [redacted].

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu. If you are a patient receiving care from the Grady Health System and have a question about your rights, you may also contact the Office of Research Administration at research@gmh.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**