CONSENT TO BE IN A RESEARCH STUDY

TITLE: A phase IV randomized, blinded-assessor, single center study to determine if administration of Sugammadex, when used to reverse deep neuromuscular blockade after open abdominal surgery, impacts hospital efficiency

PROTOCOL #: TGH015

NCT #: NCT02860507

SPONSOR:
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Suite 400
Knoxville, TN 37919

SITE(S):
Tampa General Hospital
1 Tampa General Circle
Tampa, Florida 33606
United States

FUNDED IN PART BY:
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STUDY-RELATED PHONE NUMBER(S): PI - Enrico Camporesi, MD: (813) 600-9094 (24 hours)

INTRODUCTION

The anesthesia group at Tampa General Hospital (TGH) is a part of TeamHealth Anesthesia, a nationwide clinical group. We are conducting a clinical study (a type of research study). This consent form provides information on the procedures and risks involved in this clinical study. Please read this form carefully so that you can decide if you want to take part in the study. If you join this study, you can still stop at any time.

You may want to talk to your family, friends, or primary care doctor before making your decision.

Please ask the study doctor about any questions that you may have about this study. If you do not take part in this study it will not affect your continued medical treatment.

You can find information about this research study at *http://www.ClinicalTrials.gov* , as required by U.S. law. This website will not show any information that can identify you. At most, the website will summarize the results of the study. You can search this website at any time.

PURPOSE OF THE STUDY

For your operation, you will be given a drug called rocuronium to make sure you do not move during surgery. At the end of your surgery, doctors give you a combination of two drugs (Neostigmine and Glycopyrrolate) to allow you to move again. More recently, a new drug (Sugammadex) was approved by the United States Food and Drug Administration to restore muscle movement at the end of surgery. Sugammadex has been on the European market for several years.

In this study, we would like to find out which drug (Neostigmine and Glycopyrrolate versus Sugammadex) restores muscle function faster.

You are being asked to be a part of the study because you will be having a particular type of surgery. You will be given all required medicines and treatment regardless of whether you decide to participate in the study or not.

DESCRIPTION OF THE STUDY

In this study, you will be randomly assigned to receive one of the two medications that are given as a part of your medical treatment to allow you to regain muscle movement after surgery (Neostigmine and Glycopyrrolate OR Sugammadex). After your operation, you will be given one of the drug treatments intravenously. We will collect data on the amount of time needed for your muscles to begin working again and keep track of any side effects you experience. This data will be analyzed to compare the two drugs.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

A total of 50 people at Tampa General Hospital will participate in this study.**HOW LONG WILL I BE IN THIS STUDY?**

If you meet the conditions to be a part of this study, you will be a part of the study for the entire length of your surgical procedure and for the length of your stay at the hospital. You can leave the study at any time you want to without losing any of your rights to current or future medical care at the hospital. If you decide to leave the study, we hope you will talk to the study staff to learn about any possible health or safety consequences.

WHAT WILL HAPPEN TO ME?

If you decide to participate in this study, you begin by signing this form which is your consent to take part in the research. This form is also your agreement to allow us to use your personal health information as needed in the research study. Until you have agreed to take part in the study and have signed this form, no research or measures will take place.

In order to perform surgery on you, you will be given rocuronium to paralyze your muscles for the duration of the surgery; this is a standard practice. At the end of the procedure, you will be given either a drug combination (Neostigmine and Glycopyrrolate) or the study drug (Sugammadex) to reverse muscle paralysis. Regardless of which treatment group you are assigned to, you will be regularly monitored. Your doctor and the research coordinator will be aware of whether you received the drug combination or the study drug; however, the individual who is assessing your side effects will not be aware of what drug treatment you received. This process is called blinding and helps us ensure that we collect and evaluate the data without any favoring one drug treatment over the other.

CAN ANYTHING HAPPEN TO ME? WHAT ARE THE RISKS?

As with any drugs, Neostigmine, Glycopyrrolate, and Sugammadex have side effects.

Major side effects of Sugammadex are mild headaches, nausea, irritation at the injection site, dry mouth, fatigue, cold sensation at the injection site, and oral discomfort.

Major side effects of Neostigmine are bradycardia (slower heart rate), salivation, muscle twitching, bowel cramps, or diarrhea.

Major side effects of Glycopyrrolate are dry mouth, vomiting, mild constipation, stuffy nose, sinus pain, or flushing (warmth, redness, or a tingly feeling).

WILL I BENEFIT FROM THIS RESEARCH?

If you agree to participate in this study, you may or may not receive any medical benefit. We do not know which drug treatment (Neostigmine and Glycopyrrolate OR Sugammadex) is better to reverse muscle paralysis. That is why we are doing this study.

Although you may not receive any benefit from participating in this study, medical science and future patients may benefit from your participation.

WILL I GET PAID?

We will not pay you for the time you volunteer while being in this study.

WILL IT COST ANYTHING TO BE IN THE STUDY?

It will not cost you anything to be part of the study. The costs of the study drug Sugammadex or standard medication of Neostigmine and Glycopyrrolate will be covered by research funds. All other charges will be the responsibility of you or your insurance company because you would receive these as part of your regular medical care. These are costs that are considered medically reasonable and necessary and would be part of the care you would receive if you did not take part in this study. However, you may want to check with your insurer to see if they will cover these costs.

WHAT OTHER TREATMENT CHOICES ARE THERE?

Muscle paralysis reversal is a necessary part of surgery. If you choose not to participate in the study, you will be given the drug combination of Neostigmine and Glycopyrrolate since this is a standard practice in surgery.

If you choose not to take part in this study, your care will not change in any way. Your doctor will still do his/her best to make sure that you get all of the normal care that he/she gives to surgical patients. Your choice not to be a part of the study will not be written in your medical records.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may decide not to take part or you may leave the study at any time. Not taking part or leaving the study will not lead to any penalty or loss of the benefits that you should normally have. If you decide to stop being a part of the study, we hope you will talk to your study doctor or study staff first to learn about any possible health or safety consequences.

However, your study doctor, your local institution and the sponsor of this study, have the right to stop you from being a part of the study, or cancel the study, without your consent at any time for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue the study after being told of changes in the research that may affect you;
- or for any other reason

NEW FINDINGS

You will be given any new information we learn about that might change your choice to keep being a part of the study.

WHAT HAPPENS IF I GET HURT IN THE STUDY?

If you need emergency care:

- Go to your nearest hospital or emergency room right away. Call 911 for help. It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.
- Call the study doctors as soon as you can. They will need to know that you are hurt or ill. Call Dr. Enrico M. Camporesi at 813-600-9094 or Prachiti Dalvi at 863-513-9885.

If you do NOT need emergency care:

- Go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

If you believe you have been hurt or if you get sick because of something that is done during the study, you should call Dr. Enrico M. Camporesi at 813-600-9094 immediately.

Processes and procedures regarding human research are in place to help prevent any injuries during the course of studies. Should you believe, however, that you have been hurt or if you get sick because of something that is done during the study, you should call Dr. Enrico M. Camporesi at 813-600-9094.

ADULT TAMPA GENERAL HOSPITAL INJURY STATEMENT

In the event you suffer an injury or illness as a result of participating in this research study, please be aware that immediate, short-term medical treatment for the injuries or illness will be available to you from Tampa General Hospital. The cost of the medical treatment will be billed to you to the extent not covered by your insurance company or government program or the study sponsor. No other compensation will be offered. You are not giving up any legal rights by signing this form. If you believe you have experienced a reaction to the study drug/device or have been injured as a result of research procedures performed at Tampa General Hospital, please contact the Department of Risk Management at (813) 844-7666.

Be aware that your health care payer might not cover the costs of study-related injuries or illnesses when an investigational treatment is being used.

WILL THE HOSPITAL, STUDY DOCTOR, OR MERCK BENEFIT FROM THIS STUDY?

Your doctor's practice will be compensated for their efforts to conduct this study by Merck. However, the researchers do not hold a direct financial interest in the sponsor or the product being studied. The sponsor is compensating Tampa General Hospital for storing and dispensing both drug treatments.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION (HIPAA LANGUAGE)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting FGTBA of TeamHealth to use your health information for research purposes. You are also allowing us to share your health information with individuals and organizations other than FGTBA of TeamHealth who are also involved in the research and listed below.

In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research:

- The medical staff that takes care of you and those who are part of this research study;
- The research site for this study, Tampa General Hospital;
- Any laboratories, pharmacies, or others who are part of the approved plan for this study;
- All designated review committees such as Data and Safety Monitoring Board, Tampa General Hospital Feasibility Committee/Office of Clinical Research
- Data Safety Monitoring Boards or others who monitor the data and safety of the study
- There may be other people and/or organizations who may be given access to your personal health information, including Tampa General Hospital;
- Federal offices such as the Food and Drug Administration (FDA) and Health Canada that protect research subjects like you
- Individuals at the Western Institutional Review Board
- The study doctor and the team of researchers
- Merck, who is paying for this research study.

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, FGTBA of TeamHealth and Tampa General Hospital may collect, use, and share the following information:

- Your research record
- All of your past, current or future medical and other health records held by FGBTA of TeamHealth, Tampa General Hospital, other healthcare providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to records related to HIV/AIDS, mental health, substance abuse, and/or genetic information.

By signing this form, you are permitting FGBTA of TeamHealth and Tampa General Hospital to receive, use, and share personal health information collected about you for research purposes within Tampa General Hospital health care system. You are also allowing Tampa General Hospital to share your personal health information with other individuals or organizations who are also involved in this research.

This authorization will never expire unless and until you revoke it.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW FROM THE STUDY

When you sign this consent and authorization form, you authorize or give permission for the use of your health information as described in the consent form. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

Principal Investigator: Dr. Enrico M. Camporesi

For IRB Study #
1 Tampa General Circle, Suite A-327
Tampa, FL 33606

If you withdraw your authorization, you will not be able to be in this study. If you withdraw your authorization, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. This would be done if it were necessary for the research to be reliable. You will not have access to your health information that is included in the research study records until the end of the study.

EMERGENCY AND IRB CONTACT

You have the right to ask questions about the known and unknown risks of this study at any time.

The study doctor will be available and on-call during the whole study. Please call the study doctor (Dr. Enrico M. Camporesi) at 813-600-9094 if:

- You have any questions about the study
- You experience a study-related injury
- You have a medical emergency

Contact information for Tampa General Hospital, the site of this research is as follows:
Tampa General Hospital
P.O. Box 1289
Tampa, FL 33601
813-844-7000

This study has been reviewed by an IRB and the FDA, meaning that the study was deemed ethically sound to conduct.

If you have any questions about your rights or related concerns as a research subject, or if you have questions, concerns, or complaints about the research, you may contact

IRB Name:	Western Institutional Review Board (WIRB)
Address:	1019 39th Avenue SE, Suite 120
City, State, Zip:	Puyallup, WA 98374-2115
Phone:	1-800-562-4789 or 360-252-2500
E-mail:	Help@wirb.com

Western Institutional Review Board (WIRB) is a group of people who perform independent review of research.

Western Institutional Review Board will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact Western Institutional Review Board if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Review and approval of this study by the Western Institutional Review Board is not an endorsement of the study or is outcome.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will be given a copy of this signed and dated consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had the chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

STATEMENT OF PERSON CONDUCTING INFORMED CONSENT DISCUSSION

I have fully explained the procedures involved in this study, identifying those that are investigational, and have explained their purpose. I have asked whether or not any questions have arisen regarding the investigational procedure and have answered those questions to the best of my ability.

_____

Printed Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion Date