# A Prospective Randomized Blinded Controlled Trial Comparing Clinical Outcomes in Cardiac Surgical Patients Who Receive Sugammadex vs. Placebo

Informed Consent Form

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# CONSENT FORM

***A Prospective Randomized Blinded Controlled Trial Comparing Clinical Outcomes in Cardiac Surgical Patients Who Receive Sugammadex vs. Placebo***

Principal Investigator: Steven Greenberg, MD

Principal Investigator telephone number: 847-570-1197

Sponsor: Merck

The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

**Key Information for You to Consider**

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose.** The purpose of this study is to see if a person having heart surgery will do better after surgery if an FDA approved medicine called sugammadex speeds the recovery from the muscle relaxants that have been used to prevent movement during the surgery. There is some evidence to suggest that giving this medicine might speed up recovery, but the purpose of this study is to test if there are clinical benefits compared to not using this medicine, including reducing the risk of chest infections or reducing the cost and length of stay in ICU for recovery.
- **Procedures.** Your heart surgery will be performed the same whether you participate in this study or not. If you join the study, you will be randomly selected like a flip of the coin to receive sugammadex or not receive sugammadex approximately15 minutes after admission to the ICU after surgery. Various aspects of your health and recovery will be recorded up until the time you leave the hospital.
- **Duration.** You will be involved in the study from the time you sign this consent form to when you leave the hospital after surgery. No follow-up procedures are required after you leave the hospital.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include possible nausea and vomiting, headache, and low blood pressure from sugammadex or placebo. Women of child bearing age who do not want to get pregnant should use non-hormonal means of contraception for 7 days after receiving sugammadex (or placebo-salt water).

- **Benefits**. There will be no direct benefit to you if you decide to participate in this study. You may indirectly benefit by feeling that you are helping people in the future. This study may allow healthcare professionals to learn more about how muscle relaxant reversal with sugammadex may improve clinical outcomes in patients undergoing heart surgery as it does in patients undergoing other surgeries.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

**Detailed Information about this Study:**

**Introduction:** You are being asked to volunteer for this clinical research study because you are having either an elective or more urgent heart surgery at Endeavor Health. This consent form gives information about the study so that you can talk about it with your doctor and/or family. You are being given this information to help you make your decision. If you have any questions, you can ask the study doctor or staff.

## Why is this Study Being Done?

At Endeavor, patients undergoing heart surgery receive a number of different drugs from their anesthesia care provider. Muscle relaxants, are frequently used to prevent patient movement during surgery so that the surgeons can effectively perform the surgery. Patients undergoing heart surgery are transferred to the intensive care unit after surgery, where the muscle relaxants are allowed time to wear off before removal from the breathing machine. Non-heart surgical patients may have muscle relaxant agents eliminated by a medicine called sugammadex. After heart surgery, patients at Endeavor do not routinely receive this medication and eventually the body eliminates the drug on its own while in the ICU and before removal of the breathing machine.

The purpose of this study is to see how many heart surgery patients are removed from the breathing machine within six hours after the end of surgery. The investigators will compare the time to the end of surgery to the time of removing the breathing tube in the intensive care unit in participants who either receive sugammadex (the muscle relaxant reversal) vs. those participants that do not receive sugammadex and receive salt water through the already available intravenous line that you have for the surgery. In addition, the investigators would like to see if your recovery after heart surgery is improved with sugammadex administration while you are in the intensive care unit versus those that do not get sugammadex.

Sugammadex is approved by the Food and Drug Administration (FDA), for reversal of neuromuscular blocking agents used during surgery in adults.

This study will include a total of 175 subjects at Endeavor Health. Of those subjects, approximately 152 will be randomized to receive either sugammadex or placebo.

## What Will Happen During the Study?

If you agree to participate in this study, you will be asked to sign this consent form before any research-related activities are done.

Prior to your surgery you will be randomly placed into one of two groups. Randomization is a procedure used to assign research subjects, by chance, to a study group in a clinical trial (similar to a toss of a coin, roll of dice, etc.). It is used to make sure study results are not influenced by the selection of subjects in one group as compared to another. In this study, you have a 50% chance of being assigned to one group or another. You and/or the study doctor cannot decide in which group you will be placed. Once you are assigned to a group, you cannot be switched to another group. There is a small chance that a subject may not receive the study drug. This would be due to a subject becoming ineligible during or after surgery. An example reason for ineligibility is large loss of blood during surgery.

After surgery you will be transferred to the ICU. Fifteen minutes after your arrival to the ICU the anesthesia provider will administer either sugammadex or placebo (salt water). Five minutes after administration of sugammadex or placebo and every hour after that until the breathing tube is removed, an FDA approved neuromuscular monitor (Tetragraph, Senzime, Uppsala, Sweden) will be used to monitor recovery from the neuromuscular blocking agent. The neuromuscular monitor (TetraGraph) is an FDA-approved device which measures muscle strength by applying a small electrical current to the nerves in the wrist. The device can be used by anesthesiologists and is used for patients recovering from anesthesia. However, at Endeavor, it will currently be used for this research study only.

Once you have met the standard criteria for removal of the breathing tube, the ICU team will remove the breathing tube.

Additionally, the study doctor and/or study staff will review your medical records to collect your past medical history and whether you have had any surgeries in the past. Furthermore, the study staff will record what kind of surgeries they were, your age, weight, height, what medications you have taken, as well as information pertaining to your current surgery.

**During this study, the research team will collect information about you for the purposes of this research.**

If you consent to this study, the study doctor/and or study staff will collect the following information about you:

- Medical history, surgical history, age, race sex, what type of heart surgery you are having at Endeavor, and a list of any prior and current medications that you are taking. This information will be collected for screening/eligibility purposes and to ensure that you meet all the study inclusion criteria.
- Data obtained before, during and after your surgery will include: the time of removal of the breathing tube after surgery, the time from administration of sugammadex or salt water to achieve maximum recovery of your strength prior to removal of the breathing tube, your hospital and intensive care unit lengths of stay, your cost of the ICU stay, whether the breathing tube required replacement during your hospital stay, whether you developed a chest infection during your hospital stay, and your nursing perception relating to your ICU quality of recovery within the first 24 hours of your ICU length of stay.

**How Long Will I Be in the Study?**

You will be involved in the study from the time you sign this consent form to when you are discharged from the hospital. No follow-up procedures are required.

**What Other Choices Do I Have?**

If you decide not to participate in this study you will receive standard care during your surgery. Whether you receive a muscle relaxant/neuromuscular blockade reversal drug, such as sugammadex, after surgery is determined by your doctors.

**Are There Benefits to Taking Part in the Study?**

This study may allow doctors to learn more about how neuromuscular blockade reversal with sugammadex may improve clinical outcomes in elective or urgent cardiac surgical patients undergoing cardiopulmonary bypass. Information obtained from this study may be helpful to others having the same type of surgery in the future.

**What Side Effects or Risks Can I Expect?**

The drugs used in this study might have undesired effects. Side effects may be mild or very serious. Sometimes they can be life-threatening. Some effects may go away soon after you stop taking the study drug. The study doctor will watch you carefully and will provide treatment for any effects. This may include taking you off the study or giving you other medications.

The most common side effects of sugammadex or placebo reported by ≥ 10% of adult patients are:

- Vomiting
- Pain
- Nausea
- Low blood pressure
- Headache

Uncommon side effects of sugammadex reported in adults are:

- Low heart rate (≤1%)
    - Cardiac arrest may occur in a subgroup of these patients
- Anaphylaxis (0.3%, 1 out of 299 healthy volunteers)
    - This may appear as skin reaction, rash, flushing and/or low pressure that requires medication to correct

Other side effects may happen that are not listed here or have not been seen before. Please talk to your study doctor for more details on side effects.

**Reproductive Risks:**

It is not known whether the study drugs will affect an unborn baby, a pregnant woman, or a man's sperm. You should use effective birth control methods if you or your partner can become pregnant and you wish to be in this study. If you are a female using birth control you must use

an additional, non-hormonal methods of contraception for the next 7 days following study drug administration, since it is known that sugammadex may reduce the effectiveness of hormonal contraception (like "the pill") for 7 days after it is used.

**Will My Medical Information Be Kept Private?**

Information from this study could be published in journals or presented at meetings. If either of these happen, your name and other personal information will not be used. The researchers running this study will try to keep your personal information private. Your study related information may be looked at by other doctors in this study. Your research file can also be looked at by the Endeavor Institutional Review Board, other medical personnel at Endeavor who are involved in your care, or by the Food and Drug Administration (FDA).

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.

**Will my information be used for research in the future?**

Information or specimens collected from you for this research study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, you will not be asked for additional consent.

**Protected Health Information (PHI)**

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "protected health information (PHI)." In general, under federal law, PHI is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your PHI for research and why they may need to do so.

Your PHI will only be used for the purposes described in this Consent Form. Your authorization for activities described in this section does not have an expiration date.

*What protected health information (PHI) will be used?*

- Past, present and future medical records, including information housed in the Electronic Medical Record called "Epic," which is maintained by Endeavor Health
- Information about research procedures, including office visits with your surgeon or anesthesiologist, medical tests, procedures, and questionnaires

*Who may see, use and share my PHI and why may they need to do so?*

- Endeavor research staff involved in this study
- Non-research staff within Endeavor who need this information to do their jobs (such as for treatment, payment (billing) or health care operations)

- The Endeavor IRB board that oversees the research and the Endeavor research quality improvement program
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other US government bodies that oversee or review research.
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- A group that oversees the data (study information) and safety of this research
- People or groups that we hire to do work for us, such as data storage companies, insurers and lawyers
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

Some people or groups who get your PHI might not have to follow the same privacy rules that we follow. We share your PHI only when we must and we ask anyone who receives it from us to protect your privacy. However, if your information is shared outside Endeavor, we cannot promise that it will remain private.

*Do I have the right to withdraw permission for the use of my PHI?*

You have the right to withdraw your permission for us to use or share your PHI for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. Once permission is withdrawn, you cannot continue to take part in this study. However, you will not be penalized or lose any benefits to which you are entitled.

*Do I have access to my health information?*

You have the right to see and get a copy of your PHI that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. However, to protect the study, you will not be able to see some of the study information until after the study is completed. The researchers are not required to release to you research information that is not part of your medical record.

You have the right *not* to sign this form that allows us to use and share your PHI for research; however, if you do not sign it, you cannot take part in this research study.

## Will I Be Paid for Participating?

You will not be paid for being in this study.

## Will There Be Additional Costs?

There is expected to be no additional cost to you from being in this research study. You will still be responsible for all costs that you would normally incur as part of routine care. You will still be responsible for any co-pays or deductibles as specified by your insurance plan. The study drug, salt water or sugammadex, will not be charged to you or your insurance.

## What If I Am Injured During the Study?

If you become hurt or sick because of being in this research study, you can get medical treatment at Endeavor. You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. You can ask for more information from the Research Institute of Endeavor.

Health insurance plans (including Medicare) may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

## Can I Withdraw from the Study?

Your participation in this research study is voluntary. If you decide not to be in this study, you can still get medical care as usual. If you decide to participate now, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

## What Are My Rights as a Research Subject?

You may get more information about your rights from the Chairperson of the Institutional Review Board (IRB). You can also call the IRB Coordinators at 224-364-7100. These are the people you should contact about any problems or research-related injuries that happen during the research study.

By participating in this research study you do not waive any rights to which you would normally be entitled.

## Will I Be Informed of New Information About the Study?

Any significant new information that may affect your participation will be given to you as soon as it becomes available.

## Who Can I Call with Questions?

The study doctor and staff will answer any questions you have. If you have additional questions at any time during the study, you may contact the Principal Investigator, Dr. Steven Greenberg**,** at telephone: 847-570-1197.

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**INDIVIDUAL PROVIDING EXPLANATION:**

The procedures and/or investigations described in the above paragraphs have been explained to you by:

| | |
|---|---|
| **Name of Person Explaining Study (Please PRINT)** | |
| **Signature of Person Explaining Study** | |
| **Date Study Was Explained** | |

**CONSENT TO PARTICIPATE:**

I understand that the Principal Investigator and study staff will supervise the study. I have read this consent form or have had it read to me. I understand what will happen if I enroll in this research study. I understand the possible benefits and risks of the study. I have been told about all of my treatment options. I give permission for the research study procedures described in this consent form.

I have reviewed this information with the study doctor and/or staff. I have had enough time to talk about all of my questions and concerns. I willingly consent to be a part of this study. I will receive a signed and dated copy of this Consent Form.

| | |
|---|---|
| **Subject's Name (Please PRINT)** | |
| **Subject's Signature** | |
| **Date Subject Signed** | |