UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: *A Double-Blind, Randomized, Crossover Design Study To Compare The Rocuronium Reversal By Sugammadex To Succinylcholine For Electroconvulsive Therapy (ECT)*
NCT03532178
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This is a clinical research study. Your study doctor(s), Chanhung Lee, Ronald Miller, Descartes Li, Tobias Marton and Ramotse Saunders, from the UCSF Departments of Anesthesia and Psychiatry, will explain the study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are scheduled for *Electroconvulsive Therapy* to treat depression and other mental disorders.

Why is this study being done?

The purpose of this study is to find out if a newer drug, sugammadex, can be used to help you to reverse the muscle relaxation during the *Electroconvulsive Therapy (ECT)*. ECT exerts its treatment effect by inducing generalized seizures. To protect the patients from harmful seizure injury, a muscle relaxation drug is used to control excessive muscle movement during the treatment. Since the optimal length of treatment seizure effects is brief, fast recovery of the muscle function after the treatment is desirable.

Succinylcholine has been traditionally used in ECT for muscle relaxation because of its fast recovery after the procedure, but with obvious limitations and side-effects, including in patients with muscle diseases, as well as risks of increased potassium above normal levels, increased pressure inside the eyes, causing changes in the rhythm of heart beats.

Rocuronium is a different muscle relaxant providing excellent blocking conditions and has been commonly used in surgery, but not in ECT because of its long duration of action. Sugammadex is a novel reversal drug for rocuronium, which has recently been approved by the FDA. Sugammadex can reverse the action of rocuronium on muscle relaxation. Researchers want to learn whether sugammadex can be used in combination with rocuronium to provide a timely recovery of muscle function after the ECT treatment.

This study is being funded, in part by Merck & Co, Inc., as well as UCSF departmental funds. The investigators have no financial or proprietary interests.

How many people will take part in this study?

About 50 people scheduled for Electroconvulsive Therapy will take part in this study at UCSF.

What will happen if I take part in this research study?

Before you begin the main part of the study...

You will talk to your psychiatrists and anesthesiologists in the clinic and before the procedures, and the study will be explained to you.

During the main part of the study...

On the day of the procedure, you will receive the normal ECT and standard care as you would otherwise take the treatment. There will be no change in your medical management, other than the study drugs for muscle relaxation and recording your recovery from it. You will be given the anesthesia exactly the same except the study medications for muscle relaxation and reversal.

Each participant will be on the study for two ECT treatments. You will receive Muscle Relaxant #1 (the traditionally used succinylcholine +saline) for one ECT, and receive Muscle Relaxant #2 (rocuronium + sugammadex) in the other ECT treatment period.

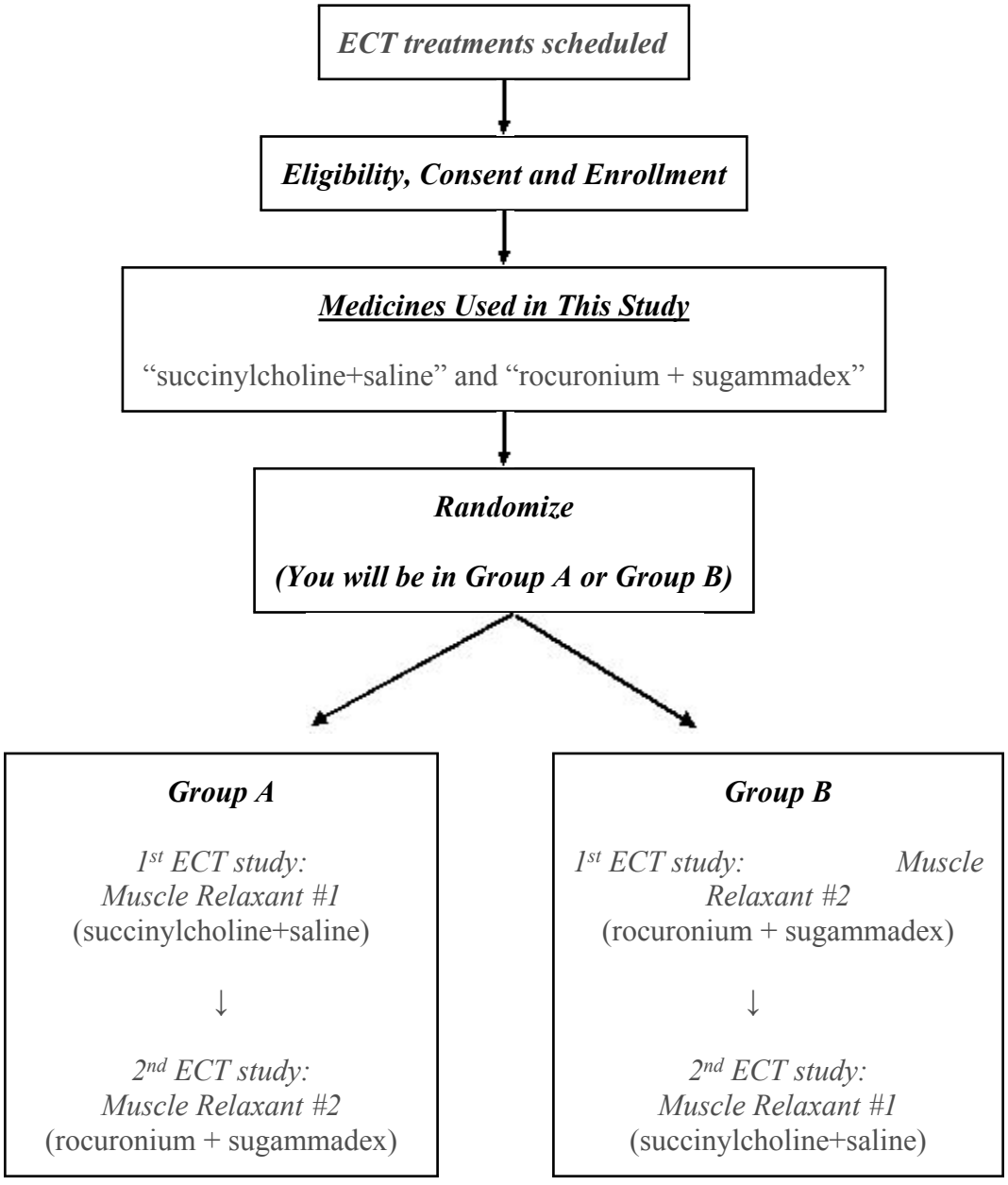
- The participants will be "randomized" to two groups:
    - **Group A** will first receive "Muscle Relaxant #1" in one ECT, then switch to "Muscle Relaxant #2" in the next study ECT treatment period
    - **Group B** will first receive "Muscle Relaxant #2" in one ECT, then switch to "Muscle Relaxant #1" in the next study ECT treatment period

- Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group. The ECT procedures will be identical, whether you are in group "A" or "B", except for the order of the study drugs.
- Double-blind means that neither the patients nor the psychiatrists or study outcome assessors know the assignment of the treatment groups, but only the anesthesiologists will know which medication is given to each patient. This procedure is utilized to prevent bias in research results.
- The time from administration of the drugs to satisfactory recovery of muscle strength will be measured in all study treatment groups. Your ECT procedure, anesthesia medications and devices, medical conditions, vital signs, time to meet discharge criteria in Post Anesthesia Care Unit will be recorded as part of your normal care.

- **Study location:** All study procedures will be done at Moffitt-Long Hospital of UCSF Medical Center as the same location where you normally receive your ECT treatment.
- You will receive a follow-up phone call to find out how you are doing on the next day after the study of your ECT procedure.

Study Plan

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



How long will I be in the study?

Participation in the study will take place in two of your ECT treatments. We would like to keep track of your medical condition for 24 hours after the treatment. We would like to do this by calling you on the telephone the next day to see how you are doing.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will help you to stop in participation.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the medication. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and side effects related to rocuronium include those, which are:

- Allergic reactions: a risk of having an abnormal reaction of the immune system to the medication. Patients will be observed for an appropriate period of time after administration.
- Muscle weakness.
- Conditions / Drugs may cause increased response or resistance to muscle relaxation.

Risks and side effects related to sugammadex include those, which are:

<u>Likely</u>

- Nausea or vomiting was reported in 12 to 26% of people having surgery.
- Increases in the blood clotting time of up to 25% was reported for up to 1 hour in healthy volunteers.
- Respiratory function monitoring and support is mandatory for patients until adequate breathing is recovered.

Less Likely

- Insomnia was reported in 5% of surgical patients.

Rare but serious

- Allergic reaction has occurred in 0.3% of healthy volunteers. Patients will be observed for an appropriate period of time after administration.
- Slow down of heart rate has been observed within minutes after administration. We will monitor for heart rate and blood pressure changes and administer treatment if clinically significant slow heart rate is observed.

Waiting times for re-administration of neuromuscular blocking agent for an emergency surgery within 24 hours after the study:

- A minimum waiting time is 5 minutes and rocuronium 1.2 mg/kg is to be administered. The onset of neuromuscular blockade from rocuronium may be delayed and the duration of neuromuscular blockade may be shortened. The recommended waiting time in patients with mild or moderate renal impairment for re-use of 0.6 mg/kg rocuronium after reversal should be 24 hours. If a shorter waiting time is required, the rocuronium dose for a new neuromuscular blockade should be 1.2 mg/kg.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

There may be no direct benefit to you from participating in this study. However, this study will help doctors learn more about *sugammadex application in ECT*, and it is hoped that this information will help in the treatment of future patients undergoing ECT treatment.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care without being in a study.

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your

participation and of any information added to your medical record as a result of your participation. Study tests and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the Sponsor: Merck & Co, Inc.
- Representatives of the University of California

Will any research-related cost be billed to me?

No. The sponsor will provide sugammadex at no cost to you.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study. In appreciation for your participation, and to help cover your parking or transportation expense, you will be given a prepaid debit card of $20.00 after each study visit is completed.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. Lee, Dr. Miller, Dr. Li, Dr. Marton or Dr. Saunders, if you feel that you have been injured because of taking part in this study. You can tell the doctors in person or call the study coordinator at (415) 476-1131. Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor *Merck & Co, Inc.*, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415-476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, 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. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor(s) Dr. Lee, Dr. Miller, Dr. Li, Dr. Marton, or Dr. Saunders, in person.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814

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.

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CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.*]*

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent