Subject Consent Form

Eastern Virginia Medical School (EVMS) Institutional Review Board

STUDY TITLE

Use of Electroconvulsive Therapy to Treat Self-Injurious Behavior in Adults with Autism Spectrum Disorders

INVESTIGATORS

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Co-Investigator: Maria R. Urbano, M.D. Dept. of Psychiatry and Behavioral Sciences, EVMS
Co-Investigator: Justin Petri, M.D. Dept. OF Psychiatry and Behavioral Sciences, EVMS
Co-Investigator: Shannon Maj, B.S., Summer Scholars Program, EVMS, MD Candidate, Class of 2017
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WHY IS THIS STUDY BEING DONE?

Self-injury is one of the strongest predictors of psychiatric hospitalization among children and young adults with Autism Spectrum Disorder (ASD). While self-injury in some patients is goal-oriented, involuntary self-injury may be a sign of a serious psychiatric illness. When medications fail, electroconvulsive therapy (ECT) is an alternative to treating psychiatric illnesses. Several case studies have used ECT to minimize the self-injury in patients with ASD where medicines don't help. This study will monitor the outcome of using ECT to treat self-injury in patients with ASD, for whom medication previously has not worked. This study will be fundamentally different from the previously investigations on the subject because this study will aim to recruit multiple participants in an open label study.

WHY ARE YOU BEING ASKED TO TAKE PART?

You are being asked to participate in this research project because you have been diagnosed with an Autism Spectrum Disorder and you have a current history of self-injury. You are at least 18 years old. You have tried and failed at least four other treatment methods to control your self-injury. You are generally healthy and there is no reason you cannot medically be treated with the electroconvulsive therapy. You have a legal guardian who can consent to medical treatment for you and a guardian or other caregiver who can attend all appointments with you.

This is a research study. This study includes only people who choose to take part. Please take your time to make your decision and feel free to ask any questions you might have.

The use of "you" in this consent form is the same as saying "your child" or a "cognitively impaired adult for whom you are a legally appointed representative."

WHAT ARE SOME IMPORTANT DETAILS ABOUT THIS STUDY?

You and your legally-appointed guardian/ caregiver will participate in a total of 18 visits over the course of 1 year. Visits 1 and 2 will occur during weeks 1 and 2. These visits will be for psychiatric and medical evaluations and will take about 1 hour each. Visits 3-14 will take place three times a week for four weeks. These visits will be for the ECT treatments and will take about 2-3 hours each. Visit 15 will take place 1 week post-treatment and visit 16 will take place 4 weeks post-treatment. Your guardian/ caregiver will keep a daily diary card between visits 1 and 16, spanning a time of 10 weeks. Visits 17 and 18 will take place at 6 months and 12 months, respectively, and take about 1 hour each.

WHEN SHOULD YOU NOT TAKE PART?

You should not take part in this study if you do not receive medical clearance from your medical doctor to receive ECT treatment. You must supply/obtain results (within the last six months) of an EKG, Chest X-Ray, Complete Metabolic Panel (CMP), Complete Blood Count (CBC), and a head CT. Dr. Patel will review the results of all the tests with you to insure you are eligible to take part. You should also not take part in this study if you have tried fewer than 4 other treatments, such as medications or behavioral therapy. Patients with preexisting cardiac illness, compromised pulmonary status, and a history of brain insult or medical complications after earlier courses of anesthesia are likely to be at an increased risk, but will not be excluded from the study, as none of these complications are absolute contraindications. You should not take part in this study if you do not injure yourself, or if your self-injury does not significantly impact your quality of life.

WHAT IS INVOLVED IN THE STUDY?

After you and your guardian provide consent and assent at the first pre-treatment appointment (Visit 1), your guardian/ caregiver will fill out the ASD Diagnostic Checklist, Repetitive Behavior Scale- Revised, and the Aberrant Behavior Checklist. The physician will complete the Self-Injury Trauma Scale, which documents the number, type, and severity of unhealed self-injury traumas. At the end of the Visit 1, your guardian/ caregiver will receive a Subject Diary Card to record the number of self-injury episodes per day, the number of aggressive episodes per day, and the perceived severity of episodes that day. The Diary Card also has space to record the medication you take every day.

The second pre-treatment appointment (Visit 2) will consist of a complete psychiatric evaluation with review of all medical evaluations. You must receive medical clearance as defined by Sentara Norfolk General Hospital and EVMS Psychiatry and Behavioral Sciences to undergo ECT treatment. We will collect the first Diary Card at this time, and give you a new Diary Card.

After receiving medical clearance, you (accompanied by your guardian/ caregiver) will begin to receive Electroconvulsive Therapy (ECT) treatments. The psychiatrist (Dr. Patel or Dr. Petri) performs the treatment in a speciallyequipped treatment room, using a special electronic instrument. The treatment consists of passing a small, carefully controlled electric current between two electrodes that are applied to the two sides of your head at the temples. The treatments are usually given in the morning before breakfast. Once in the treatment room, the patient is given an intravenous anesthetic, which induces sleep within a matter of a few seconds. Also, medication is given to help muscular relaxation. The purpose of these medications is to allow the muscles to be relaxed so that any muscle activity occuring during treatment will be barely measurable. This precaution helps protect you from complications, which might include fractures or dislocations. You should not experience discomfort or pain during the treatment and will not feel the electric current. A mouth guard will be placed in your mouth before the electricity begins, to protect against oral/dental trauma. You should not have any memory of the treatment. When the treatment is given you will be asleep and experience generalized muscular contractions the same as a seizure These contractions, which have been softened by the intravenous medication, last approximately 60 seconds. Minutes later, you will slowly awaken and may experience brief confusion, similar to that seen in persons emerging from any type of anesthesia. When you are ready and the doctor agrees, you will be permited to be up and about.

You will receive ECT 3 times a week for 4 weeks, for a total of 12 treatments (Visits 3- 14). All ECT treatments will take place in the Outpatient Surgery and Diagnostic Unit of Sentara Norfolk General, and will be performed by Dr. Shriti Patel or Dr. Justin Petri. The first ECT treatment (Visit 3) will determine how much electric current is needed to cause a seizure (seizure threshold). Subsequent ECT treatments (Visits 4-14) will be determined by the acting physician based on your seizure threshold. Following the procedure, you will recover in the Post Anesthesia Care Unit.

Throughout the course of the treatment, your guardian/ caregiver will continue filling out the Diary Card. Once treatment begins, your guardian/ caregiver will also write any side effects of the treatment noted by themselves or by you. Your guardian/ caregiver will turn in and receive new Diary Cards weekly.

After the ECT treatment is complete, you and your guardian/ caregiver will return to the EVMS Department of Psychiatry and Behavioral Sciences for post-treatment appointments (Visits 15-18). At these post-treatment appointments your guardian/ caregiver will complete the ASD Diagnostic Checklist, Repetitive Behavior Scale- Revised, and the Aberrant Behavior Checklist. The physician will complete a second Self-Injury Trauma Scale. At this time the Diary Card will be collected and subjects will receive Diary Cards for 1 month. Visits 15-18 will occur at 1 month, 2 months, 6 months, and 12 months post – acute ECT treatment.

The following chart is a summary of what you will do during the study:

		Appointment Type	To-Do	Diary Card
Week 1	Visit 1	Pre- ECT Appointment	Consent and Assent forms, Release of Medical Information, ADC, RBS-R, ABC, Self-Injury Trauma Scale	Receive Diary Card 1
Week 2	Visit 2	Pre- ECT Appointment	Psychiatric Evaluation, Medical Clearance	Return DC 1, Receive DC 2
Week 3	Visit 3	ECT	Determine Seizure Threshold	Return DC 2; Receive DC 3
	Visit 4	ECT	Treatment	
	Visit 5	ECT	Treatment	
Week 4	Visit 6	ECT	Treatment	Return DC 3; Receive DC 4
	Visit 7	ECT	Treatment	
	Visit 8	ECT	Treatment	
Week 5	Visit 9	ECT	Treatment	Return DC 4; Receive DC 5
	Visit 10	ECT	Treatment	
	Visit 11	ECT	Treatment	
Week 6	Visit 12	ECT	Treatment	Return DC 5; Receive DC 6
	Visit 13	ECT	Treatment	
	Visit 14	ECT	Treatment	
Week 7	Visit 15	Post- ECT visit	ADC, RBS-R, ABC, Self-Injury Trauma Scale	Return DC 6; Receive DC 7, 8, 9, 10
Week 11	Visit 16	Post- ECT visit	ADC, RBS-R, ABC, Self-Injury Trauma Scale	Return DC 7, 8, 9, 10
6 Months	Visit 17	Follow-up visit	ADC, RBS-R, ABC, Self-Injury Trauma Scale	
12 Months	Visit 18	Follow-up visit	ADC, RBS-R, ABC, Self-Injury Trauma Scale	

ADC – ASD Diagnostic Checklist; **RBS-R** – Repetitive Behavior Scale Revised;
ABC – Aberrant Behavior Checklist; **DC** – Diary Card

WHAT ARE THE RISKS OF THE STUDY?

Headache, mild muscle soreness, or nausea sometimes occurs, but these are infrequent and usually respond to simple treatment. As the treatments progress, a certain amount of haziness of memory develops. This memory impairment is usually temporary and should clear up within weeks following the last treatment. There are occasional remaining areas of memory impairment, but this is not common.

Electroconvulsive Therapy (ECT), like any other medical or surgical procedure, involves a certain amount of risk. Careful medical evaluation of each case will be completed to ensure that there are no overriding medical reasons not to have the treatment. Deaths are extremely rare, but may occur due to heart problems or a prolonged seizure. Risk of mortality is 1 in 10,000-80,000. Cardiovascular complications such as cardiac arrest, arrhythmias, hypertension, and hypotension are rare but may occur. Complications, although infrequent, may also include fractures and/or dislocations of bones or adverse reactions to intravenous medications. Oral or dental trauma may occur as a result of the seizure. In some patients with bipolar disorder, manic symptoms may emerge or worsen with ECT. Efforts to protect you from complications are taken through the use of medications. However, these may sometime occur in spite of all precautions and must be looked upon as a recognized risk of treatment. If such a complication occurs, appropriate treatment will be instituted.

Inadvertent release of PHI is also a potential risk to the subject.

For more information about risks, ask Dr. Urbano or Dr. Patel, or contact the Department of Psychiatry and Behavioral Sciences at 757-446-5888.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. There is no guarantee that you will personally benefit from taking part in this study. Results of ECT are beneficial in most cases, but there may be some cases that do not respond as equally well. As in all forms of medical treatment, some patients will recover promptly, some only moderately well, and others may fail to respond at all. We hope the information learned from this study will benefit other people with Autism Spectrum Disorders and Self-Injurious Behavior in the future.

WHAT OTHER OPTIONS DO YOU HAVE?

Instead of being in this study, you may choose <u>not</u> to participate in this research study. You may continue with your current psychiatrist and try different medication or behavioral interventions. You also have the right to obtain a second opinion before starting ECT, which may be done by contacting another psychiatrist of your choice.

WHAT ABOUT CONFIDENTIALITY?

The information gathered from the study will be held in strict confidence to be used only for research purposes and your identity will not be disclosed in any publications or articles that may be written about the results of these experiments. To ensure confidentiality, all study records will be coded by a random number and your name will not appear anywhere on these data. In accordance with Eastern Virginia Medical School research policies, all records will be kept in a locked file. This research study will <u>not</u> involve the release of your identifiable medical information. All protected health information will be maintained in strict confidence as required by law. However, your protected health information may be

released if required by law. Once your protected health information is released, federal privacy laws may no longer protect the information.

- You also have the right to review your research records, or someone you choose may review your research records on your behalf, once the study has ended unless the law says you can't do this.
- Any research information in your medical record will become a permanent part of that document.

Your study records may be reviewed and/or copied in order to meet state and/or federal regulations. Reviewers may include, for example, an Eastern Virginia Medical School Institutional Review Board, the U.S. Food and Drug Administration, and the Office for Human Research Protections.

ARE THERE LIMITS TO CONFIDENTIALITY?

If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they may report such information to authorities to prevent harm to subjects or others.

No research materials will be provided to any scientists not listed on the front page of this form with any information that would identify you. Except for information released to prevent serious harm, the investigators will do everything they legally can to protect your privacy.

WHAT WILL PARTICIPATION IN THE STUDY COST OR PAY?

This study will not cost any additional charges beyond the usual physician and hospital charges for receiving ECT. The tests required for medical clearance are necessary for all patients in order to be eligible for ECT and will be charged to the participant's insurance. The cost of ECT treatment will also be charged to the participant's insurance. The participant will be responsible for any insurance copays resulting from medical clearance testing and/or ECT.

WHAT IF YOU GET INJURED?

In the case of injury or illness resulting from this study, emergency medical treatment is available and will be provided by Drs. Patel, Petri, or Urbano and billed to you and/or your insurance. Further medical care and/or hospitalization resulting from this injury or illness will be your responsibility.

Eastern Virginia Medical School will not provide free medical care for any sickness or injury resulting from being in this study. Financial compensation for a research related injury or illness, lost wages, disability, or discomfort is not available. However, you do not waive any legal rights by signing this consent form.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Taking part in this study is your choice. If you decide not to take part, your choice will not affect any medical benefits to which you are entitled. You may choose to leave the study at any time. If you do leave the study, discuss it with the attending psychiatrist who will help you do so in the safest way. If you leave, the study it will not result in any penalty or loss of benefits to you.

The investigator may decide to take you off this study if you cancel your approval, if it is in the best interest of your health, new information becomes available, or your condition worsens. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions about the study, contact the investigators, Shriti Patel, M.D. or Maria Urbano, M.D., at 757-446-5888. If after business hours, the phone number listed here will give you directions to call the 24 hour answering service.

For questions about your rights as a research participant, contact a member of the Institutional Review Board through the Institutional Review Board office at (757) 446-8423. You may also contact Betsy Conner, Director, EVMS Human Subjects' Protection Program & IRB Office, (757) 446-5854.
If you believe you have suffered an injury as a result of your participation in this study, you should contact the principal investigator, Dr. Shriti Patel, 757-446-5888.

SIGNATURE

YOU WILL GET A COPY OF THIS SIGNED FORM. YOU MAY ALSO REQUEST INFORMATION FROM THE INVESTIGATOR. BY SIGNING YOUR NAME ON THE LINE BELOW, YOU AGREE TO TAKE PART IN THIS STUDY AND ACCEPT THE RISKS.

_____ Signature of Participant	_____ Typed or Printed Name	_____ Relationship to Subject	___/___/___ MM/ DD/ YY
_____ Signature of LAR if applicable	_____ Typed or Printed Name	_____ Relationship to Subject	___/___/___ MM/ DD/ YY

STATEMENT OF THE INVESTIGATOR OR APPROVED DESIGNEE

I certify that I have explained to the above individual the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the above to the volunteer on the date stated on this consent form.

_____ Signature of Investigator or Approved Designee	_____ / _____ / _____ MM/ DD/ YY