UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

Transcranial Electrical Stimulation in Stroke EaRly After onset Clinical Trial- Bridging and Adjunctive Neuroprotection (TESSERACT-BA)

A prospective, randomized, single center study to assess the safety, tolerability, feasibility, and preliminary efficacy of transcranial direct current stimulation (tDCS) in acute ischemic stroke undergoing endovascular thrombectomy.

INTRODUCTION

Mersedeh Bahr Hosseini M.D., and associates from the Departments of Neurology at the University of California, Los Angeles are conducting a research study.

The researchers will explain this study to you as a patient or legally authorized representative of a patient with lack of capacity to make decisions at this time. **Research studies are voluntary and include only people who choose to take part or people whose their legally authorized representative gives permission to participate on their behalf.**

You can discuss this study with others including family members before making your decision, however, please note that if you are undergoing clot removal procedure it is crucial to minimize the time to the procedure (endovascular thrombectomy) in order to reduce the disability from stroke. Therefore, your decision making to participate in this study as the patient or patient's legally authorized representative is extremely time sensitive.

When reading the rest of this form, please note that the words "you" and "your" refer to the person in the study rather than to a legally authorized representative who will, or who might, sign this form on behalf of the person in the study.

The research team is asking you to be in this study because you have been diagnosed as having had an ischemic stroke within the past few hours and you have additional presenting features. An ischemic stroke is an injury to the brain caused by a blood clot inside a blood vessel blocking blood flow to part of the brain. The additional features you have that make you eligible for this study include that: 1) you have undergone clot-removal procedure through groin and have some blockages left in brain blood vessels; or 2) you will be undergoing clot-removal procedure through groin; and 3) you have contraindications to treatment with clot-dissolving drugs.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine if electrical inhibitory fields, applied by transcranial direct current stimulation (tDCS), are safe, well-tolerated, feasible to deliver, and potentially improve final outcome in acute ischemic stroke when used after and/or before clot removal procedure.

A weak inhibitory electrical field will be applied after an incomplete clot removal procedure to save the brain cells that are still not receiving enough oxygen and nutrients due to remaining blood vessel blockage.

Depending on the day on which you are enrolled, a weak inhibitory electrical field may also be applied before the clot removal procedure enable the brain cells to tolerate the low blood flow state, and therefore more brain tissue left to be saved by clot removal procedure.

This study is being funded by the UCLA Department of Neurology Stroke Program.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 48 patients will take part in this study at UCLA.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you take part in this study, the researcher(s) will ask you to:

Protocol ID:IRB#19-000529 UCLA IRB Approved Approval Date: 4/27/2021 Through: 4/21/2022 Committee: Medical IRB 3

If you have already undergone the clot removal procedure with remaining blood vessel blockage (incomplete clot removal) you will be asked to:

1) Have a cloth cap with electrodes placed on your scalp. You will be randomly assigned to the active current or the control group, with a 75% chance of receiving the active current and 25 % chance of being in control group.
   If you are assigned to the active group depending on the day on which you are enrolled, you may be receiving 20 minutes of stimulation once (session 1) or twice (session 2) after the clot removal procedure.
   If you are assigned to the control group, depending on the day on which you are enrolled, you will receive a weak electrical stimulation lasting only a few seconds once (session 1) or twice (session 2) after the clot removal procedure ends.

2) After each of the 1 or 2 sessions, answer 10 questions about how you feel, and have a brief, 5 minute examination of your neurologic function (strength, sensation, vision, language, coordination) performed by a study physician or coordinator.

3) Have brief follow-up assessments at 24 hours (in person), day 4 (in person), day 30 (by phone), and day 90 (in person). At the 24 hour, day 4, and day 90 assessments, you will have a brief, 5 minute examination of your neurologic function (strength, sensation, vision, language, coordination) performed by a study physician or coordinator. At the day 4, day 30, and day 90 assessments, you will also have a 5 minute interview during which you will be asked about your degree of recovery, including resumption of work and social activities.

If you are undergoing clot removal procedure you will be asked to:

1) Have a cloth cap with electrodes placed on your scalp. You will be randomly assigned to the active current or the control group, with a 75% chance of receiving the active current and 25 % chance of being in control group.
   If you are assigned to the active group, you will receive up to 20 minutes of inhibitory electrical current to the brain via the scalp electrodes (session 1) before the clot removal procedure.
   If assigned to the control group, you will receive instead a weak electrical stimulation lasting only a few seconds once before the procedure. Delay in clot removal procedure is likely to worsen the outcome of stroke, therefore, this session only lasts until the clot removal procedure can be initiated.

2) Only if the clot removal procedure results in an incomplete clot removal, you will receive 20 minutes of stimulation twice (session 2 and 3) after the clot removal procedure.
   If assigned to the control group, you will receive instead a weak electrical stimulation lasting only a few seconds twice after the procedure.

4) After each of the 1, 2, and 3 sessions, answer 10 questions about how you feel, and have a brief, 5 minute examination of your neurologic function (strength, sensation, vision, language, coordination) performed by a study physician or coordinator.

5) Have brief follow-up assessments at 24 hours (in person), day 4 (in person), day 30 (by phone), and day 90 (in person). At the 24 hour, day 4, and day 90 assessments, you will have a brief, 5 minute examination of your neurologic function (strength, sensation, vision, language, coordination) performed by a study physician or coordinator. At the day 4, day 30, and day 90 assessments, you will also have a 5 minute interview during which you will be asked about your degree of recovery, including resumption of work and social activities.

You will not receive any stimulation during the clot removal procedure.

HOW LONG WILL I BE IN THIS STUDY?
This study will last 90 days.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

Known risks and discomforts associated with the study treatment:
--Transcranial direct current stimulation may cause minor tingling, itchiness, or redness of the scalp.
--Known complications of acute stroke in patients receiving standard care including endovascular thrombectomy include brain swelling, neurologic deterioration, stroke progression, brain hemorrhage, pneumonia, seizures, and death. Among the first 30 patients receiving transcranial direct current stimulation in US and French trials, 1 patient had a fatal hemorrhage. About 15% of patients with acute stroke receiving endovascular thrombectomy have neurologic worsening in the first 24-48 hours after admission.

Known risks and discomforts associated with CT and MRI:
You will be having CT or MRI's done as part of usual stroke care and we will be looking at them to make decisions.
If you receive MRI, while no significant risks have been found from the use of MRI scans, you may be bothered by the MRI machine noise and by feelings of being closed in (claustrophobia). The contrast agent you will receive is FDA-approved and used routinely for MRI exams. It contains a material called gadolinium.

- Aside from a slight pin prick when the needle is inserted into your vein, about 1 in 100 people may notice discomfort, tingling or warmth in the lips, metallic taste in the mouth, tingling in the arm, nausea, or headache. These symptoms go away quickly.
- There is a small risk of an allergic reaction to gadolinium. However, a severe allergic reaction occurs in less than one in 300,000 people.
- People with severe kidney failure who receive gadolinium are at risk of formation of too much connective tissue in the skin and internal organs (Nephrogenic Fibrosing Dermopathy). This is a serious disease, which can result in death. You should notify the study team or MRI staff if: you are allergic to gadolinium or you have kidney problems

If you can't receive MRI due to reasons such as presence of metal in your body or history of allergic reaction to gadolinium, you will be receiving CT instead. This test involves radiation, however, the cumulative radiation exposure from this test is considered small and is not likely to adversely affect you or your disease. It is possible that having several of these tests may add to your risk of injury or disease. When deciding to enter this study, think about your past and future contact with radiation. Examples of contact with radiation include x-rays taken for any reason or radiation therapy for cancer treatment.
An intravenous contrast material is used with this study and you will feel a slight pin prick when the needle is inserted into your vein. You may have a warm, flushed sensation during the injection of the contrast materials and a metallic taste in your mouth that lasts for a few minutes. Occasionally, a patient will develop itching and hives, which can be relieved with medication. If you become light-headed or experience difficulty breathing, you should notify the technologist or nurse, as it may indicate a more severe allergic reaction.

Unknown risks and discomforts:
The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me:
There is a possibility that, if you are assigned to the active tDCS group by chance, the tDCS application reduces stroke size and improve functional outcome, but whether it will do so is unknown and you may not benefit from the tDCS. There is no guarantee that you will receive any medical benefit as the result of participation in this study. It is possible that your condition may improve, it may stay the same or it may get worse from participation in this study.

Possible benefits to others or society:
This study will help the researchers learn more about the safety, tolerability, feasibility, and potential benefit of tDCS in acute stroke patients. This information may help in the treatment of future patients with strokes like yours.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?
Whether or not you participate in this study, you will receive all proven treatments for acute ischemic stroke for which you qualify. These standardly available treatments include intravenous fluids, anti-clotting medicines (such as aspirin or heparin), and blood pressure regulation.

[ ] **Continued participation after improvement in cognitive status**
If the above box is checked, you were enrolled in the study by permission from your next of kin or legally authorized representative because, at the time of your enrollment, you were not able to consent for yourself. Now that you have regained capacity to consent, you are being asked whether you want to continue in the research study and have the following two options (please place a check to indicate your preference):

[ ] Wish to continue in the study

[ ] Do not wish to continue in the study

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?
The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about you up to the point of withdrawal will remain part of the study and may not be removed from the study database.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?
The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:
Strongly identifying personal information about you (e.g. name, medical record number) will be kept on a separate, local computer file and not entered into the study database. The linking local computer file will be maintained on UCLA firewall-protected computer, accessed only by study personnel.

How information about you will be stored:
Paper records will be kept in locked file drawers in a locked room, to which only authorized research personnel have access. Confidentiality of your records is guarded by assigning you with a research identifier number/code, so that the data are stored in computer files (except for a single tracking file) without reference to your name, hospital registration number, or any other type of highly personally-identifiable information (e.g., birth date, social security number, etc.).

People and agencies that will have access to your information:
The research team, authorized UCLA personnel, and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

How long information from the study will be kept:
Study data with highly-identifying information removed will be maintained permanently as a resource to plan future studies to develop new treatments for stroke patients. The data could be used for future research studies

or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?
The study will pay for the cost of supplying and administering the study device, and all required study items and services as described in this consent form.

WILL I BE PAID FOR MY PARTICIPATION?
You will not be paid for your participation in this research study.

WILL THE INFORMATION COLLECTED AS PART OF THE STUDY BE DISCLOSED TO ME?
The study procedures include routine tests for treating and monitoring your condition and the results of these tests will be provided to you**.**

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:
You may contact Dr. Bahr Hosseini at 310-794-6379 with any questions or concerns about the research or your participation in this study. You can also call the UCLA Page Operator at (310) 825-6301 to reach Dr. Bahr Hosseini 24 hours a day, 7 days week.

UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: mirb@research.ucla.edu or U.S. mail: UCLA OHRPP, 11000 Kinross Ave., Suite 211, Box 951694, Los Angeles, CA 90095-1694.

Public Information about this Study:
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call her at the number listed above.
If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For more information about this, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: mirb@research.ucla.edu or U.S. mail: University of California Los Angeles,10889 Wilshire Blvd, Suite 830; Los Angeles, CA 90095-1406.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?
Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at anytime.
- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant'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.

SIGNATURE OF THE PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF THE LEGALLY-AUTHORIZED REPRESENTATIVE

_____
Name of Legally-Authorized Representative

_____ _____
Signature of Legally-Authorized Representative Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date