NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: **M**ulti-arm **O**ptimization of **S**troke **T**hrombolysis (**MOST** Stroke Trial)

Sponsor/Protocol Principal Investigator: **Opeolu Adeoye, MD – Washington University in St. Louis; James Grotta, MD – Memorial Hermann Hospital**

Performance Site Principal Investigator: Scott Kasner, MD

Performance Site: The Hospital of the University of Pennsylvania

INTRODUCTION

If you are being asked to give permission for someone else to be in this study, you should try to determine whether that person would want to be in the study. "You" throughout this form refers to that person.

You are having a stroke caused by a clot blocking blood flow to the brain. The standard treatments to remove or dissolve blockages causing stroke are helpful within the first few hours of a stroke. You are already being treated with the clot busting medicine tPA (also called alteplase) or TNK (also called tenecteplase) which are the standard treatments. Even with tPA or TNK treatment, however, the blood vessels sometimes block up again when tPA or TNK wears off. This can worsen the stroke. This study is designed to find out whether adding one of two blood-thinning medicines helps keep blood vessels open and decrease the impact of the stroke.

You are an appropriate candidate for this study, but you do not have to be in it. It is your choice. Either way you will be treated with the standard stroke care. If you decide to be in the study, you can stop participating at any time.

This form tells you about the study. Please ask questions about anything that you do not understand.

WHAT IS THE STUDY ABOUT?

The MOST study is designed to find out whether adding one of two blood-thinning medicines (argatroban or eptifibatide) to tPA or TNK helps to decrease the impact of strokes and if it is safe. Earlier studies combining tPA with argatroban or eptifibatide have shown that it seems safe and may be helpful to add argatroban or eptifibatide to tPA (standard treatment) to help dissolve clots causing stroke.

Argatroban and eptifibatide are United States (US) Food and Drug Administration (FDA)-approved blood thinners, but they are not approved for treating strokes. Intravenous (IV) tPA is FDA-approved to treat stroke. TNK is not FDA-approved to treat stroke, however, new data showing similar safety and efficacy as tPA has led to it being used as standard treatment in the US. Using argatroban or eptifibatide with tPA or TNK is regulated by the US Food and Drug Administration (FDA) but not approved for standard treatment.

HOW IS THIS DIFFERENT FROM WHAT WILL BE DONE NORMALLY?

The standard medications for treating stroke are t-PA or TNK (clot-busters) through the vein (also called “IV”). Doctors sometimes also remove clots using a device. Patients are monitored closely, and medications are used to treat blood pressure and cholesterol, to keep the patient stable, and to reduce the risk of future strokes. Rehabilitation is also standard treatment. This study does not change any of this treatment. It is only being done to see if adding argatroban or eptifibatide is helpful and is safe.

The MOST study has three groups. All three groups get standard treatment with tPA or TNK. In addition, Group A gets a placebo (salt water) solution through an IV (with no eptifibatide or argatroban); Group B gets argatroban through an IV; Group C gets eptifibatide through an IV.

HOW IS IT DECIDED WHICH GROUP YOU WILL GO IN?

A computer will assign you randomly to 1 of the 3 study groups. This means the computer will put you into a group by chance. As the study goes on, if one drug does not appear to be as effective as the other, it may be given less frequently or not at all. You will not know which group you are in.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

You will get standard stroke treatment no matter which group you are in. This includes tPA or TNK with or without clot removal by a device, blood pressure and cholesterol treatments, rehabilitation, and any other treatments your doctor recommends.

In addition, you will get the investigational treatment for 12 hours. If you are assigned to,

- Group A, you will get IV placebo (salt water)
- Group B, you will get IV argatroban
- Group C, you will get IV eptifibatide

We will collect the results of tests that you have as part of your standard treatments for your stroke. You may also get two additional blood tests, one at 2 hours and one at 6 hours after initially receiving the study drug

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THE STUDY?

You may or may not directly benefit from being in this study. It is possible but unknown whether adding these medicines will help reduce the impact of your stroke. The knowledge gained from this study may help doctors learn more about what treatments are most effective for stroke.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART IN THE STUDY?

If you are assigned to standard treatment plus placebo, there are no added treatment-related risks. If you are assigned to standard treatment plus argatroban or eptifibatide, the most common risk or side effect of both medicines is bleeding. Possible major risks include bleeding in the brain, worsened or new stroke, allergic reaction, and death. Other bleeding can also occur such as bleeding in your stool or urine and bleeding from IV sites. You may have a bruise (black and blue mark) or pain where we

take blood samples. There is also a small risk of feeling lightheaded, fainting, or infection. Preliminary studies of adding argatroban or eptifibatide to tPA did not show increased risk of bleeding, however there could be increased risk with these treatments. There may be unknown risks.

As data suggest TNK and tPA have similar bleeding risks, TNK risks and side effects in combination with argatroban or eptifibatide are likely to be similar to tPA. However, the risks and side effects of TNK in combination with argatroban or eptifibatide are unknown.

WHAT WILL BE REQUIRED OF PARTICIPANTS?

Your participation will last about 3 months. Regardless of which group you are in, you will have 4 follow-up checks. These may be in-person or over the phone and involve physical exams and asking questions. The 3-month follow-up visit should be in-person and should include a video recording of how you are doing.

WHAT IS THE ALTERNATIVE TO BEING IN THE STUDY?

The alternative to being in this study is to be treated with standard treatment (tPA or TNK).

WHAT HAPPENS IF YOU ARE HARMED BY BEING IN THE STUDY?

If you become ill or injured from participating in this research study, emergency medical care will be provided to you. The Hospital of the University of Pennsylvania will decide on a case by case basis whether to reimburse you for your out of pocket health care expenses. You or your third-party payer may have to pay for these costs.

The funding agency, the National Institutes of Health (NIH), and the National Institute for Neurological Disorders and Stroke (NINDS), will not pay for any medical treatment for injuries that occur during his study or are caused by participation.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

The study will pay for your study treatments. The study will not pay for the standard medical care that you receive during the study. These costs will be billed to you or your insurance.

WILL YOU BE PAID FOR BEING IN THE STUDY?

You will not be paid for being in this study.

WHAT CAN I EXPECT FROM THE RESEARCHERS?

If at any time the researchers find out about unexpected risks or dangers to you or others in the study, they will inform you and may remove you from the study if needed, in accordance with standard medical practice. They will also honor any decision you make to withdraw from the study at any time. Your medical care will not be compromised in any way.

WILL YOUR INFORMATION BE KEPT PRIVATE?

The Hospital of the University of Pennsylvania will keep your information private and follow all research regulations. We will use a code rather than your name to label your information, and we will not identify you in research reports. Your records may be reviewed by study sponsors, the federal Food and Drug Administration (FDA), Health Canada (government agency similar to the FDA), StrokeNet Central Institutional Review Board (CIRB) as allowed by research regulations. The CIRB is a group that looks out for the rights and welfare of research participants.

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier outside of NIH StrokeNet.

There is a slight risk in any research study that your personal information could be accidentally released to people who are not supposed to have it.

Your health information will be stored and shared with other researchers. The information will be available for any research question, such as research to understand what causes strokes, or development of new scientific methods.

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the investigator learns about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

WHOM CAN I CONTACT IF I HAVE QUESTIONS OR CONCERNS?

If you have questions about this research study or to report a research-related injury, you can contact the researcher Scott Kasner, MD at 215-349-5990

Please call the StrokeNet Central Institutional Review Board (CIRB) at 513-558-5259 (Monday – Friday 8 am to 5 pm) if you:

- Think the research has hurt you.
- Have questions about giving consent or your rights as a research participant.
- Have questions, concerns, or complaints about the research.
- Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

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.

CONSENT:

Please print your name, sign, and date below if you agree to be in the study. You will be given a separate HIPAA (Health Insurance Portability and Accountability Act) Authorization form, to review and will be asked to sign, that details your authorization to use (disclose) your Health Information for Research Purposes. The HIPAA Authorization form provides privacy standards to protect patient's medical records and other health information. By signing this consent and separate HIPAA Authorization form, you will not give up any of your legal rights. You will receive a copy of the signed and dated consent document to keep for your records and reference.

_____	_____
Name of Participant (PRINT)	Telephone Number
_____	_____
Signature of Participant (18 or older with capacity to consent)	Date

OR

_____	_____
Name of Legally Authorized Representative (PRINT)	Telephone Number
_____	_____
Signature of Legally Authorized Representative	Date

_____

Relationship or Authority of Legally Authorized Representative to Participant

Person Obtaining Consent

I attest that the requirements of informed consent for this research project have been satisfied – that the Experimental Subject's Bill of Rights, if appropriate, has been provided and that I have discussed the research and explained in non-technical terms all of the information in this consent form, including risks and adverse reactions that may be expected. I encouraged the participant to ask questions and that all questions asked were answered.

_____

Name of Person Obtaining Consent (PRINT)

_____ _____

Signature of Person Obtaining Consent Date

WITNESS STATEMENT:

The participant or LAR is unable to read or sign this consent form because of the following reason(s):

___ The participant or LAR is non-English speaking.
___ The participant or LAR is illiterate.
___ The participant or LAR is visually impaired.
___ The participant or LAR is physically unable to sign the consent form. Please describe:
_____
___ Other (please specify): _____

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

_____

Name of Impartial Witness (PRINT)
(may be interpreter if participant/LAR is non-English speaking)

_____ _____

Signature of Impartial Witness Date