t-PA Prophylaxis to Reduce Central Venous Catheter Associated Infection and Thrombosis (TOPCAT)

NCT03672006

November 20, 2019

Statement of Volunteer Consent and Health Insurance Portability and Accountability Act (HIPAA) Authorization for Research Study

Study Title: t-PA Prophylaxis to reduce Central Venous Catheter Associated Infection and Thrombosis

Principal Investigator(s) / Study Leader(s): Sheila J. Hanson, MD
The Principal Investigator is the Study Leader for this research.

Phone Number(s): 414-266-3728

Full Street Address: 9000 W. Wisconsin Avenue, MS 681, Milwaukee, WI 53226

E-Mail Address: shanson@mcw.edu

Co-Investigator(s): Rowena Punzalan, MD 414-937-6896
Rainer Gedeit, MD 414-266-3360

"You" refers to you or your child throughout the consent form.

- **We are asking you to be in a research study.**
- **You do not have to be in the study.**
- **If you say yes, you can stop the study at any time.**
- **Your health care will not change in any way if you say no.**
- **Feel free to ask questions.**
- **Take as much time as you need to make your choice.**
- **Only sign this form if you want to be in the study.**

A. Why are we asking you to be in this research study?

We invite you to take part in this research study to learn more about people like you who have central lines placed while they are in the hospital. A central line is a long, thin, flexible tube in your body that gives you medicine, fluids, nutrients or blood. Sometimes central lines can stop working well because they are clogged with the material that makes up blood clots (fibrin), sometimes the blood vessel the central line is in can get a blood clot. Both fibrin and blood clots can increase the risk of an infection in the

Effective Date: November 20, 2019
Expiration Date: November 19, 2020
Children's Hospital of Wisconsin IRB

central line. There is a medication, a tissue plasminogen activator, which is used to unclog central lines when they stop working. This medicine is also called t-PA, Alteplase, or Activase®. We don't know the best way to prevent these clogs from occurring but wonder if this medicine, t-PA, used ahead of time while the line is working well would help prevent blood clots, line blockage, and line infections. Because it will take many children with central lines at many hospitals to get enough data to answer this question, this first study is called a 'pilot study,' where we will only include children at Children's Hospital, to see if our way of doing the study is smooth for the patients and investigators before expanding to other hospitals.

This study will help us learn more about how to keep central lines working well. We will study 20 children, less than or equal to 18 years old who have central lines while they are in the pediatric ICU at Children's Hospital of Wisconsin. We will see if t-PA works better than the medicine used now (heparin) in to prevent line blockage, blood clots and line infections. We will decide if this is the best study design for a bigger study for these problems.

.

B. What happens if you say yes, you want to be in this study?

- If you say yes, you will be "randomized" into one of the two study described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. You will have an equal chance of being in each group. Using randomization improves the chance of determining which (if either) treatment is better. Whichever group you are in, a medicine will be put into the central line and let sit for 30 min-4 hours depending on when your next medicine through the line needs to be given.
    - If you are in Study group 1: you will get t-PA in your central line
    - If you are in Study group 2: you will get heparin in your central line.
    - We will not know which group you are in.
- The study medicine will be put in your central line every 3 days until you leave the ICU, a month has passed, or you no longer need your central line and it is taken out of your body.
    - If you do get a line clot or infection or any reaction to the medicine, the study will stop at that time, and your providers will care for you as normal clinical care.
    - At the end of the study, you will have an ultrasound of your body where your central line is to see if there are any blood clots.

Effective Date: November 20, 2019
Expiration Date: November 19, 2020
Children's Hospital of Wisconsin IRB

- Ultrasound is a painless picture that can see if your blood vessels look normal.

How long will the study take?

You will be actively participating in the study until you receive 10 doses of either heparin or t-PA, are discharged from the PICU or have the CVC removed. We will then monitor your medical chart for 30 days following the last dose of either heparin or t-PA or 7 days after the CVC is removed, whichever occurs first. If you are discharged home from the hospital with the CVC in place we will follow your medical chart for 7 days after discharge.

If you turn 18 years old while still participating in this research study, we will have you sign a consent form as an adult if you wish to continue study participation.

C. Can anything bad happen to you because of this study?

Yes, there is a chance that:

- You could have an allergy to the medication, or bleeding. The amount of study medicine will just fill your central line and so risk to your body is low. The risk of the study medicine, t-PA, is the same as the standard medicine, heparin. If you have significant problems with bleeding, or if you are currently taking blood thinners such as coumadin, heparin injections or high dose aspirin you should not be part of this study. In addition, this study drug may not work for you.
- During the ultrasound you may feel slight pressure in the area where the ultrasound probe is passed over your body.
- Someone could find out that you are in the study and learn something about you that you did not want others to know.
- You could have a legal problem if you told us about a crime, such as child abuse (or other mandatory reporting) that we have to report.

We will do our best to protect your privacy.

D. Will this study help you in any way?

We do not know if there will be a direct benefit to you or not. Benefit may include a decreased risk of central line infection or blood clots (thrombosis). This study will help us to gain knowledge to design a multicenter interventional study to develop therapy to reduce the risk of central line infection or thrombosis. There is evidence that these complications result in unfavorable outcomes, such as,

Effective Date: November 20, 2019
Expiration Date: November 19, 2020
Children's Hospital of Wisconsin IRB

increased length of mechanical ventilation, increased length of stay, increased healthcare cost and increased mortality.

E. Will you be paid for being in this study?

You will not be paid for being in this study.

F. Will it cost you anything to be in this study?

There will not be a cost to you for participating in the study. If your doctor decides to order an ultrasound for clinical reasons, then this will be charged as a normal expense to your insurance. If we complete the ultrasound for research purposes only then the study will cover this cost. The study will also cover the cost of the heparin or t-PA treatment.

In the event that this research activity results in an injury, the care for such injuries will be billed in the ordinary manner to you or your insurance company.

Insurance companies may refuse to pay for injuries sustained while participating in a research study. If you think that you have suffered a research-related injury, let the study physician know right away so she can evaluate you. We will not give you money to treat any injury from the study, but if you are hurt in this study, treatment will be provided.

G. Do you have to participate in this study?

No, you do not have to be in this study**.** You can stop being in the study at any time. Just let Dr. Hanson know.

If you say no,

- Your health care will not change in anyway.
- The other choices if you don't want to be in this study are to just receive heparin or no medicine to try and keep your central line from clogging.

If you stop being in this study, we may still use the study information we have already collected as long as it cannot be linked back to you. Any data collected or analysis that has been done up to this point will need to be kept due to legal and regulatory requirements. The investigator may terminate subject's participation in the study without regard to subject's consent if attending physician thinks that study participation may affect the patient's health or welfare.

H. What if you have questions?

If you have questions or there is something you do not understand, please call the Dr. Hanson 414-266-3728 or Katherine Siegel 414-266-3973. Please call if you have:

- Any questions about the study.

Effective Date: November 20, 2019
Expiration Date: November 19, 2020
Children's Hospital of Wisconsin IRB

- Concerns that you have been injured in any way by being in this study. Dr. Hanson will evaluate you for any research related injuries you report.
- Questions about how we will use your information.

You can also call the Institutional Review Board (IRB) if you have any questions about your rights as a research subject. The IRB is the committee that has reviewed this study. A member of this committee can talk to you if you have any questions or complaints at 414-337-7133.

I. RESEARCH DATA IN MEDICAL RECORD

A copy of the signed consent, assent and HIPAA Authorization will be kept in your medical record. We will be collecting information on your condition and hospital stay for this study. The ultrasound report performed at the end of the study will be part of your medical record. No other data collected for the study will be placed in your medical record.

J. Will your information be kept private?

The only people allowed to see your information will be the people who work on the study and people who make sure the study is done the right way and hospital rules are followed. Groups or people that might look at and/or copy your research records are:

- Dr. Hanson, the research team and the statisticians who will help figure out what the results mean
- The Institutional Review Board at Children's Hospital of Wisconsin
- Food and Drug Administration (FDA)

Your health information, and a copy of this form will be locked in our files. When we share the results of the study in a medical journal or at a conference talk we will not include any information that identifies you. We will do our best to make sure no one outside of the study will know you are a part of the study. As this is FDA-regulated research, they may inspect and/or copy your research records for purposes of quality assurance and data analysis.

A description of this clinical trial will be available in http://www.clinicaltrials.gov, as required by US 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.

K. Permission to collect, use and share your health information.

The health information we are asking for is called "Protected Health Information" (PHI). It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA).

Researchers are required to get written permission from you to use your health information in a research study, data registry bank, and/or a tissue bank. As this is FDA-regulated research, FDA has access to review and copy all relevant records.

How will your health information be used?

Your health information will be used to provide information needed for the research study.

What information will be used?

The following information about your health will be used for this research study: medical history, laboratory results, ultrasound results and what happens during this hospital stay.

Who will use your health information?

The hospital or clinic that holds your medical records will share medical information with the researchers.

How long will the permission last?

This authorization will last until the end of the study.

You can end this Authorization at any time by withdrawing your permission in writing. Beginning on the date your permission ends, no new health information from you will be used. Any health information that was shared before you withdrew your permission will continue to be used. After this Authorization ends, you can no longer actively take part in this research study.

Withdrawal of your permission should be made in writing to the person whose name is listed here:

Sheila Hanson, MD, 9000 W. Wisconsin Avenue, MS 681, Milwaukee, WI 53226

How will your health information be protected?

Whenever possible your health information will be kept confidential. Federal privacy laws, however, may not apply to some people outside of CHW who can share your health information without your permission.

Additional information.

You should take as much time as you need to make your decision about giving permission for the use of your health information for this research study. The researchers are required by law to report child abuse or neglect (or suspicion of abuse or neglect) if you or your child mention it to the researchers or if it is suspected. Please ask any questions you may have about this authorization.

L. Permission for you to participate in this study

This study, consent form and HIPAA Authorization has been explained to you by:

_____	----------
Name Of Study Leader or Study Team Designee	**Signature of Study Leader or Study Team Designee**
_____	_____
Date	**Time**

Sign this document if:

- **You have read (or had it read to you) this entire consent form.**
- **We have talked with you about the information in this form and have answered your questions.**
- **You agree to let the study team use and share your health information for this study.**
- **You agree to let your primary care doctor share your health information with us.**
- **You agree to be in this study.**

After you sign this document, we will give you a copy of this form.

_____	----------
<u>Printed</u> Name of Study Participant or Authorized Representative	**Date**

Effective Date: November 20, 2019
Expiration Date: November 19, 2020
Children's Hospital of Wisconsin IRB

_____ ----------

Signature of Study Participant or Authorized Representative **Date**

ASSENT OF MINOR:

The above has been explained to me and I agree to participate.

_____ ----------

Signature of Minor **Date / Time**

If child's assent is not obtained above, please indicate reason below (check one):

☐ **Assent is documented on a separate IRB-approved assent form**

☐ **Child is under the required age range for assent**

☐ **The IRB granted a waiver of assent, please specify: ----------**

_____ ----------

Signature of Principal Investigator or Research Team Designee **Date**

_____

Time