MCC-18-14244
Pilot Study on the Reduced Intravenous Fluids to Improve Clearance of High-Dose Methotrexate (HDMTX) in Children with Lymphoma or Acute Lymphoblastic Leukemia

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RESEARCH PARTICIPANT CONSENT FORM

TITLE: Pilot Study on Reduced Intravenous Fluids to Improve Clearance of High-Dose Methotrexate (HDMTX) in Children with Lymphoma or Acute Lymphoblastic Leukemia

PROTOCOL #: MCC-18-14244

VCU IRB #: HM20016430

SPONSOR: VCU Massey Cancer Center

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If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say “you” in this consent form, we mean your child; “we” means the doctors and other staff.

If you are an emancipated minor, or if you agreed to take part in this study as a child but have since turned 18, your consent is required to take part. If you are age 13 to 17 years old, your assent (agreement) is required to take part in this study. When we say “you” in this consent form, we mean you, the patient.

INTRODUCTION

This consent form will tell you about this research study, which is also called a clinical trial. Your study doctor or study team will explain the research study to you. Research studies only include people who choose to take part. You have the option to not participate. You may take home an unsigned copy of this consent form so that you can discuss the study with your family or friends before making your decision. You may also discuss it with your health care team. If you have any questions, ask your study doctor or study team for more explanation. Please take your time to make your decision about taking part in this study.

OVERVIEW AND KEY INFORMATION

Taking part in this study is your choice

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

Why is this study being done?

Usually, people who receive high-dose methotrexate to treat their cancer are also given large amounts of fluids through a tube that goes into one of their veins (IV) to help the methotrexate

move through or “clear” from their bodies. These large amounts of IV fluids can cause fluid to build up in different parts of the body, causing side effects like weight gain, fluid in the lungs, and swelling in the arms or legs. The purpose of this study is to test the safety of giving a smaller amount of IV fluids and to find out what effects, if any, that has on people.

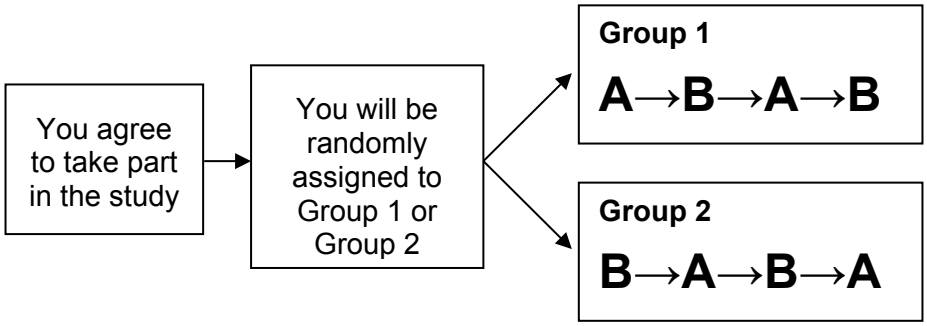
Up to 24 people will take part in this study.

What is the usual approach to treating my cancer?

You are being asked to take part in this study because your doctors have decided to give you high-dose methotrexate to treat your lymphoma or acute lymphoblastic leukemia. You will be given IV fluids as part of that treatment. People who are not in a research study may still be treated with high-dose methotrexate and IV fluids.

What will happen if I participate in this study?

During this study, you will receive up to 4 doses of methotrexate, one every 2 weeks. After each dose of methotrexate you will receive either the standard (larger) amount of IV fluids or the smaller amount. For the first dose, you will be randomly assigned (like the flip of a coin) to receive either the standard (larger) or smaller amount of IV fluids. The next time you receive methotrexate, you will be assigned to the other fluids group. The chart below shows how you will go back and forth between amounts of fluids for each of your 4 doses of methotrexate. Start reading at the left side and read across to the right.



A = standard (larger) amount of IV fluids **B** = smaller amount of IV fluids

What other tests and procedures will I have if I take part in this study?

If you decide to take part in this study, the exams, tests, and procedures you will have are part of the usual approach in treating patients who receive high-dose methotrexate and IV fluids for lymphoma or acute lymphoblastic leukemia. Your study doctor or study team will tell you about these. The results of some of the usual exams, tests, and procedures will be used for the research purposes of this study. Your study doctor or study team will review the number of days you stay in hospital, costs and charges each time you get high-dose methotrexate.

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

If you decide not to take part in this study, you have other choices. For example:

- You may choose to receive high-dose methotrexate without being in the study or to have another type of treatment, if any are available for your type of cancer

- You may choose to take part in a different study, if one is available
- Or you may choose not to be treated for cancer

How long will I be in this study?

You will be in the study until after you have received up to 4 doses of methotrexate, one every 2 weeks. Some side effects may mean you have to wait longer between doses. About 3 weeks after your last dose of methotrexate, at your regular follow-up visit, the study team will collect the last information needed for the study.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

You will receive other drugs and treatments as part of your care before and after you get methotrexate. Your study doctor or study team will tell you about the side effects of high-dose methotrexate and those other treatments, and you will be asked to sign a consent form that describes the risks of methotrexate treatment.

Your study doctor or study team will be testing your blood and will let you know if changes occur that may affect your health. Here are important points about side effects:

- Your study doctor or study team do not know who will or will not have side effects
- Some side effects may go away soon, some may last a long time, or some may never go away
- Some side effects may be serious and may even result in death

The table below shows a side-by-side comparison of the risks of the standard (larger) amount of IV fluids and the risks of the smaller amount of IV fluids.

Standard (larger) amount of IV fluids	Smaller amount of IV fluids

• Weight gain
• Fluid around lungs
• Difficulty breathing
• Swelling of arms, legs
• Extra time for the methotrexate to leave your body, resulting in:
  – extra time in the hospital *and/or*
  – extra methotrexate side effects like mouth sores
	• Abnormal kidney tests
	• Decreased kidney function
	• Extra time for the methotrexate to leave your body, resulting in:
	  – extra time in the hospital *and/or*
	  – extra methotrexate side effects like mouth sores

Extra time in the hospital is always a risk of getting methotrexate, whether you get the standard (larger) amount of IV fluids or the smaller amount. This extra time might be about 7 days. Ask your doctor if you have any questions about this.

Reducing the amount of IV fluids may involve risks that are currently unknown or unforeseeable. This means that there may also be possible risks of giving the smaller amount of IV fluids that researchers do not yet know about.

Here are important points about how you and your study doctor or study team can make side effects less of a problem:

- Tell your study doctor or study team if you notice or feel anything different so they can see if you are having a side effect
- Your study doctor or study team may be able to treat some side effects
- Your study doctor or study team may adjust your methotrexate dose or amount of IV fluids to try to reduce side effects

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

Benefits

Getting a smaller amount of IV fluids may lower your chance of having side effects that happen with the normal (larger) amount of IV fluids. This could mean you will have a decreased chance of weight gain, fluid in your lungs (which may cause difficulty breathing), swelling of arms and legs, and/or methotrexate side effects like mouth sores – but we do not know if this will happen or not. This study may help researchers learn things that may help other people in the future.

CAN I STOP TAKING PART IN THIS STUDY?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information for the purpose of the study.

The study doctor or study team will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. The study doctor may stop the study treatment or take you out of the study:

- If your health changes and the study is no longer in your best interest
- If you have serious side effects that require you to stop according to the rules of the study
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor or the institutional review board (IRB), which is a group of people who review the research with the goal of protecting the people who take part in the study

WHAT ARE MY RIGHTS IN THIS STUDY?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You cannot lose medical care or any legal rights by agreeing to participate in this study.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You and/or your health plan/insurance company will be billed for all standard costs of treating your cancer, including the cost of the IV fluids, as well as tests, procedures, medicines, or hospital admissions to manage any side effects.

You will not be paid for taking part in this study.

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

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor or study team. Your study doctor or study team will talk with you about your options for medical treatment.

Fees for such treatment will be billed to you or to your health plan/insurance company. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. The study will not pay for medical treatment.

To help decrease the risk of injury or illness, it is very important to follow all directions provided by your study doctor or study team.

WHO WILL SEE MY MEDICAL INFORMATION?

Your privacy is very important to us. The researchers will make every effort to protect it. However, some of your medical information may be given out if required by law. If this happens, the researchers will do their best to make sure that any information that is released will not identify you.

Your research information and your personal identifying information will be kept private through the use of password-protected electronic files, locked research areas, and study identification numbers. The results of this research may be presented at meetings or in publications, but you will not be identified by name. In general we will not give you any individual results from this study.

In the future, identifiers (such as your name and birthday) might be removed from the information you provide in this study. After that removal, the information could be used for other research studies by this study team or another researcher without asking you for your consent again.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- Virginia Commonwealth University (VCU)
- VCU Institutional Review Board (IRB)
- Food and Drug Administration (FDA)
- National Cancer Institute (NCI)

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

The Health Insurance Portability & Accountability Act (HIPAA) of 1996 provides for the protection of your health information from unauthorized use and disclosure. This section tells

you what health information about you may be used and given out in the study and who may give and receive the information. By signing the consent form for this study, you agree that health information that identifies you may be used and disclosed as needed for this research.

Authority to Request Protected Health Information

The following people and/or groups may request your protected health information:

- Principal investigator and research staff
- Study sponsor
- Research collaborators
- VCU IRB
- Data and Safety Monitoring Committee
- Government/health agencies
- Others as required by law

Authority to Release Protected Health Information

The VCU Health System (VCUHS) may release the information identified in this authorization from your medical records and provide this information to:

- Health care providers at the VCUHS
- Principal investigator and research staff
- Study sponsor
- Research collaborators
- Data coordinators
- VCU IRB
- Data and Safety Monitoring Committee
- Government/health agencies
- Others as required by law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Type of Information that may be Released

The following types of information may be used for the conduct of this research:

- Complete health record
- Diagnosis and treatment codes
- Discharge summary
- History and physical exam
- Consultation reports
- Progress notes
- Laboratory test results
- Complete billing record
- Itemized bill

Expiration of This Authorization

This authorization will expire (end) when the research study is closed, or when there is no need to review, analyze, and consider the data generated by the research study, whichever is later.

Right to Revoke Authorization and Re-disclosure

You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this authorization you may no longer be allowed to participate in the research study. To revoke this authorization, you must write to the principal investigator.

WHERE CAN I GET MORE INFORMATION?

You may visit the NCI website at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS STUDY?

The investigator and study staff listed below are the best persons to contact about any questions or concerns you have about this study or to report side effects or injuries.

Cady Noda, PharmD, BCPS: 804-828-4070

You can also contact a study team member at 804-628-2112.

You may contact the VCU Office of Research for any of the following:

- Questions about your rights as a participant in this or any other research
- To discuss any problems or concerns
- To get information or offer input about research
- To speak to a person who does not work directly with your study doctor and the study team
- If you cannot reach your study doctor or a member of the study team

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
804-827-2157; https://research.vcu.edu/human_research/volunteers.htm

STATEMENT OF CONSENT AND/OR PARENT/LEGAL GUARDIAN PERMISSION

I have been provided with an opportunity to read this consent/permission form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent/permission form, I have not waived any of the legal rights or benefits to which I or my child otherwise would be entitled. My signature indicates that I freely consent to participate or give permission for my child to participate in this research study. I will receive a copy of the consent/permission form for my records.

Consent and Assent Instructions:

Consent: For participants under 18, consent is provided by the parent or guardian. At least one parent or guardian must sign, but 2 may sign if desired.

Emancipated minors and participants 18 years and older must provide consent using the **Emancipated Minors or Re-Consenting New Adults** box on the next page.

Assent: Documentation of assent is required for participants ages 13 through 17 using the **Assent by Child** box on the next page. Participants age 7 through 12 will be given a separate age-appropriate assent form. Assent is not required for subjects under age 7.

Signature Block for Enrolling Child Participants - Parent/Guardian Permission	
_____ Name of Child/Youth Participant	
_____ Name of First Parent/Legal Guardian (Printed) *Study team – verify that this individual is the child's parent or legal guardian.*	
_____ **Required** First Parent/Legal Guardian Signature	_____ Date
_____ **Optional** Second Parent /Legal Guardian's Signature	_____ Date
_____ Name of Person Conducting Parental Permission Discussion (Printed)	
_____ Signature of Person Conducting Parental Permission Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Signature Block for Enrolling Child Participants (Ages 13-17) – Assent by Child

STATEMENT OF ASSENT BY CHILD PARTICIPANT

The person doing this research study has explained what will happen to me if I participate in this study. My signature below means that I want to be in this study. I can decide not to be in this study if I do not want to. Nothing will happen to me if I do not want to participate.

_____ _____

Child Participant's Signature Date

_____

Name of Person Conducting Assent Discussion (Printed)

_____ _____

Signature of Person Assent Discussion Date

_____ _____

Principal Investigator Signature (if different from above) Date

Signature Block for Emancipated Minors or Re-consenting New Adults

_____

Adult Participant Name (Printed)

_____ _____

Adult Participant's Signature Date

_____

Name of Person Conducting Consent Discussion (Printed)

_____ _____

Signature of Person Conducting Consent Discussion Date

_____ _____

Principal Investigator Signature (if different from above) Date

Signature Block for Short Form Consent: Participants with Limited English Proficiency
_____ Name of Participant (Printed) _____ _____ Witness or Interpreter's Signature Date *(NOTE: The witness may be the interpreter or a family member of the LEP subject who can speak both English and the participant's language. The witness cannot be the member of the study team conducting the consent process.)* _____ Name of Person Conducting Consent/Assent Discussion (Printed) _____ _____ Signature of Person Conducting Consent/Assent Discussion Date _____ _____ Principal Investigator Signature (if different from above) Date