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Subject Consent Form

Macon & Joan Brock Virginia Health Sciences at Old Dominion University Institutional Review Board

STUDY TITLE

PARENTERAL LACTATED RINGER'S PLUS DEXTROSE 5% VS. LACTATED RINGER'S IN LABOR: A RANDOMIZED CONTROLLED TRIAL ON MATERNAL AND NEONATAL OUTCOMES

Key Summary of Information

We are inviting you to take part in a research study about the effects of intravenous fluid during labor. The goal is to evaluate how these fluids affect labor duration, maternal health and newborn outcomes. This page is intended to provide you with key information to help you decide whether or not to participate. The detailed consent form follows this page. Please ask the research team questions. If you have questions later, the contact information for the principal investigator in charge of this study is below.

WHAT IS THE PURPOSE, WHAT ARE THE PROCEDURES, AND WHAT IS THE DURATION OF THIS STUDY?

The purpose of this study is to compare two types of standard intravenous (IV) fluids (Lactated Ringer's with 5% Dextrose vs. Lactated Ringer's alone) and if they impact the time from induction to delivery to assess potential effects on both mother and baby. If you participate, you will be randomly assigned to receive either alternating solutions of D5 (Dextrose 5%) and LR (Lactated Ringer's) or LR alone, administered intravenously from the start of labor induction until delivery. Health data on both you and your baby will be collected throughout labor and delivery. The study procedures will only take place during your labor, with no additional follow-up visits required after discharge.

WHAT ARE SOME REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY?

By participating, you contribute to advancing knowledge in maternal and neonatal care. While there may not be direct benefits to you and to your baby, this study could improve outcomes for future patients.

WHAT ARE SOME REASONS YOU MIGHT CHOOSE NOT TO PARTICIPATE IN THIS STUDY?

Some reasons you might choose not to participate in this study include the potential risks associated with the fluids being tested, such as neonatal hypoglycemia (low blood sugar). If these risks or inconveniences are concerning to you, you might decide not to participate. For a complete description of the risks of this study, please refer to detailed consent form.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in the study, it should be because you really want to volunteer for it. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. You may withdraw from the study at any time, and you will receive standard care/treatment.

WHAT IF YOU HAVE QUESTIONS OR CONCERNS?

For questions about the study, contact the investigator, Dr. Tetsuya Kawakita, at 757-446-7900.

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.

Please continue to the next page for detailed information about the study.

Study Title

Parenteral Lactated Ringer's Plus Dextrose 5% vs. Lactated Ringer's in Labor: A Randomized Controlled Trial on Maternal and Neonatal Outcomes

INVESTIGATORS

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WHY IS THIS STUDY BEING DONE?

The purpose of this study is to understand whether intravenous fluids containing 5% dextrose (D5) combined with Lactated Ringer's (LR) can shorten the time from labor induction to delivery compared to LR alone. The study will also examine the effects of these fluids on neonatal glucose levels.

WHY ARE YOU BEING ASKED TO TAKE PART?

You are being asked to participate because you are at least 37 weeks pregnant, undergoing labor induction, and meet the eligibility criteria for the study. Your child's health outcomes will also be monitored as part of the study.

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.

WHAT ARE SOME IMPORTANT DETAILS ABOUT THIS STUDY?

At this local site, about 129 people will take part in this study. A total of about 258 people are expected to take part in this study at 2 sites throughout the United States and Italy. We will need you to be in the study for the duration of your labor and delivery, which will vary.

Clinically relevant research results will be disclosed to participants, including any that might apply individually. If significant findings arise during the study, such as changes in neonatal outcomes like hypoglycemia, participants will be informed promptly. Additionally, participants will be given the option to discuss these findings with their healthcare providers.

WHEN SHOULD YOU NOT TAKE PART?

If you have any of the following conditions listed below, you should not take part in this study:

- Spontaneous labor (cervical exam between 5-6 cm) with or without ruptured membranes
- Favorable cervix as determined by your doctor (Bishop score >6 or cervix >= 5cm)
- Diabetes mellitus (both gestational and pre-gestational)
- Structural kidney disease, such as
    - Polycystic kidney disease (PKD)
    - Glomerulonephritis
    - Interstitial nephritis
- Acute or chronic kidney disease resulting in abnormal creatinine or protein in the urine

- Evidence of Chorioamnionitis (infection of placenta and amniotic fluid) or non-reassuring fetal testing (category 2 tracing) at the time of enrolling
- Fever (>38.0 °C) at the time of enrolling
- Stillbirth
- Planned cesarean delivery

WHAT IS INVOLVED IN THE STUDY?

You will be "randomized" into one of the study groups described below. This means that you will be assigned into a group by chance. It is like flipping a coin. A computer program may do this - neither you nor the investigator will be able to choose what group you will be in. You will have an equal chance of being placed in either group.

The following are standard procedures/treatments that will be done because you will be in this study:

- Induction of labor (method determined at the discretion of the attending physician).
- Monitoring of vital signs, contraction patterns, cervical dilation, and fetal heart rate throughout labor.

These will be done under hospital supervision.

The following are experimental procedures/treatments that are being tested in this study:

- Administration of either a 5% dextrose solution mixed with Lactated Ringer's (D5/LR) or Lactated Ringer's (LR) alone, depending on the group to which you are assigned.
- Measurement of neonatal glucose levels after birth. Neonatal glucose measurements are part of standard clinical care. The total volume of blood drawn will be approximately 1 mL, which is within safe limits for neonatal blood collection.

These will be done under hospital supervision. The study will also include the collection of data from your medical record to evaluate maternal and neonatal outcomes.

WHAT ARE THE RISKS OF THE STUDY?

A risk associated with allowing your data to be saved is the release of personal information from your study record. We will strive to protect your records so that your personal information (like name, address, social security number and phone number) will remain private.

Neonates born to women in the intervention group (D5/LR) may be at an increased risk of hypoglycemia due to possible maternal hyperglycemia. All neonates will be checked for hypoglycemia, regardless of assigned study group.

Risks and side effects related to the intravenous fluid administration we are studying include:

- Fluid overload
- Blood pressure changes
- Neonatal hypoglycemia (low blood sugar levels)
- IV infiltrate

Blood draws to assess sodium and glucose levels may cause:

- Fainting
- Infection
- Bruising
- Swelling and pain at the site of the blood drawing

Neonatal glucose monitoring after birth may lead to:

- Minor discomfort for the baby

While on the study, you are at risk for these side effects. These are still rare side effects, occurring in approximately less than 10% of cases. You should discuss these with the investigator and/or your regular doctor or healthcare provider. Other drugs may be given to make side effects less serious and make you more comfortable. Many side effects go away shortly after the intravenous fluid administration is immediately stopped, serious side effects such as death or ICU admission are rare. There also may be other side effects that are unknown and we cannot predict.

For more information about risks and side effects, ask the investigator or contact your regular doctor/health provider.

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. However, by participating, you may help researchers learn more about the effects of different fluid treatments during labor induction, which could lead to improved management of labor and delivery for future patients. We hope the information learned from this study will benefit other people with similar pregnancy-related conditions in the future.

What Other Options Do You Have?

Instead of being in this study, you have these options*:*

- You may choose to undergo labor induction using standard fluids typically used in the hospital, such as Lactated Ringer's solution, without the addition of dextrose.
- You may also choose not to participate in this study and receive the usual care and interventions provided in the hospital, according to the standard protocols.

Please talk to your regular doctor or health care provider about these and other options.

What about Confidentiality?

In conducting this research study, it may be necessary for the research team to send information about you and your health to persons in other organizations. This information may include what we call "protected health information (PHI)," which includes personal information about you. It will be shared with others only as described below:

Description of Your PHI to Be Disclosed	Organization and Person (or their title) Disclosing Your PHI	Organization and Person (or their title) Receiving Your PHI	Purpose of Disclosure
Name, DOB, address, Medical history, health records related to the study, study-related treatments or interventions, any other personal information relevant to the study	Macon & Joan Brock Virginia Health Sciences/EVMS Medical Group Allscripts medical records	The PI and members of the research team	For the purpose of the research study
Maternal and Neonatal outcomes	Sentara EPIC	The PI and members of the research team	For the purpose of the research study

All protected health information will be maintained in strict confidence as required by law. However, your protected health information may be disclosed if required by law. Once your protected health information is disclosed for research, such as to the sponsor, federal privacy laws may no longer protect the information.

- If you refuse to give your approval for your personal information to be shared as described in this consent form, you will not be able to be in this study. However, your choice will not affect any medical benefits to which you are entitled.
- By signing this consent form to participate in the study, you are allowing the research team to share PHI, as described in this consent form.
- You have the right to cancel your approval for the sharing of PHI. If you cancel your approval, you will have to leave the study. All information collected about you before the date you cancelled will not be used for the purpose of the research. To cancel your approval, you must notify Dr. Tetsuya Kawakita in writing to 825 Fairfax Avenue, Suite 310 Norfolk, VA 23507.
- Your approval for the sharing of personal information about you for this study does not expire at the end of the study.
- You also have the right to review your research records, or someone you designate may review your research records on your behalf, once the study has ended unless prohibited by law.
- 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, Macon & Joan Brock Virginia Health Sciences Institutional Review Board or the U.S. Food and Drug Administration (FDA).

Information learned from this research may be used in reports, presentations and publications. None of these will personally identify you.

WHAT WILL PARTICIPATION IN THE STUDY COST OR PAY?

There are no additional costs to you associated with taking part in this study.

You will receive a total of $50 in the form of a GreenPhire Clincard prepaid debit card. This is to help cover your expenses and inconvenience.

If any new products, tests, or discoveries resulting from the research have potential commercial value, you will not be compensated or benefit financially.

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 medical personnel at Sentara Norfolk General Hospital and paid for by you or your health insurance. Further medical care and/or hospitalization resulting from this injury or illness will be charged to you or your health insurance.

Macon & Joan Brock Virginia Health Sciences at Old Dominion University 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 ABOUT THE COLLECTION OF DATA/TISSUE/SPECIMENS?

You are in a study where identifiable data and blood samples (including lab results) are collected as part of your participation in the research study. The blood samples will not be used or distributed for future research studies by the investigator or other researchers. After all of the study testing is complete, the specimens will be destroyed.

Right now, there are no plans to use the data for another research study. However, the identifiers might be removed and, after such removal, 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.

Data will typically be used by researchers and their collaborators. Data may be provided to for-profit and not-for-profit entities outside Macon & Joan Brock Virginia Health Sciences at Old Dominion University; however, Macon & Joan Brock Virginia Health Sciences at Old Dominion University will only be paid reasonable costs associated with the collection and processing of data. There is no anticipated profit.

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 investigator 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 or it is in the best of your health or D5/LR is not available.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Virginia law says that if you or anyone associated with the study is exposed to the other person's body fluids that might transmit the virus that causes AIDS or the Hepatitis B or C virus:

- The person whose body fluids were involved is deemed to have consented to testing for those viruses so that no further consent is necessary to test the person for these diseases; and,
- Those test results will be released to the person who was exposed and to the health department as required by Virginia law.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions about the study, contact the investigator, Dr. Tetsuya Kawakita at 757-446-7900.

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.

If you believe you have suffered an injury as a result of your participation in this study, you should contact the principal investigator, Dr. Tetsuya Kawakita at 757-446-7900. You may also contact Betsy Conner, director, Macon & Joan Brock Virginia Health Sciences at ODU Human Subjects Protection Program and IRB office, at (757) 446-5854.

FDA CLINICAL TRIAL REGISTRATION

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.

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

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