Official Title: Hospital Waterbirth: A pilot randomized control study

NCT05175599

IRB Approval Date: 02/28/2023

Advocate Aurora Health IRB Stamp of Review	*Complete or apply a patient label*
AAH IRB #: 20-176 Version date: 1/23/2023	Medical Record #

Subject name: _____ Subject date of birth: _____

Advocate Aurora Health
Consent to Participate in a Research Study

Study Title	Hospital waterbirth: A pilot randomized control study
Study Investigator	Emily Malloy, PhD, CNM, APNP [redacted] (daytime) [redacted] (24-hour contact number)

Why am I being asked to participate?
You are being asked whether you would like to voluntarily participate in a research study about waterbirth because you are an English speaking, healthy, low-risk, pregnant adult being seen for prenatal care (25 weeks 0 days to 34 weeks 0 days gestation) by midwives and obstetricians at Advocate Aurora Health, Aurora Sinai Medical Center.

This form describes the study and what you would need to do. We will answer any questions you may have so that you can make an informed decision.

What is a research study?
A research study is an experiment, survey, or information collection whose purpose is to answer a specific question, such as:

- Does this work?
- Is it safe?
- What kind of treatment is better?
- How do people think or feel about this?

To answer these questions, doctors, nurses, and scientists need volunteers to participate in research studies. These volunteers are called "subjects." The doctors, nurses, and scientists who run the research study are called "investigators." Other people who help them run the study are called the "research team."

A research study has specific rules the investigator must follow. The study rules may say that subjects can't receive certain medications or treatments while they are in the study. We will explain the rules you will have to follow. If you can't or don't want to follow these rules, then you should not participate.

What is the purpose of this study?
In this study, we want to find out if using a labor tub filled with warm water during labor and for birth will help impact your pain and influence your birth experience.

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Where will this study take place?
This study will take place at Advocate Aurora Health, Aurora Sinai Medical Center. We expect to enroll and randomize about 186 subjects to either waterbirth or land birth.

What is involved?
As a subject, you will be responsible for:

- attending all prenatal and study visits, as well as completing all prenatal labs
- telling the investigator if there are any changes in your pregnancy during the study
- telling the investigator if you have any changes in medications during your pregnancy and the study
- following the directions of the investigator and research team during your labor and birth
- completing *The US Birth Satisfaction Scale Revised (US-BSS-R)* questionnaire post-delivery
- postpartum follow-up

If you agree to take part in this study, you will sign this consent form before any study-related procedures are performed. The investigator and research team will ask you questions and review your medical record to see if you qualify to be in the study.

If you meet all criteria to be in this study, you will be randomized to one of two groups. Randomized means being assigned to a group by chance, like flipping a coin or drawing names out of a hat. You have a 66.5% chance (or a 2 out of 3) of being assigned to the waterbirth group (Group 1) and a 33.5% chance (or 1 out of 3) of being assigned to the land birth (i.e., normal care) group (Group 2). Group 1 will have the option of using the tub to labor and give birth in. Group 2 will have usual midwifery and obstetric care during labor and will give birth on land. Individuals in group 2 will not have an option to use a water tub for delivery. You cannot choose which group you will be in. We will tell you which group you are in during your prenatal care and it will be noted in your chart.

The following are part of regular medical care. This means you will have these whether you choose to be in this study or not.

- All regular prenatal labs
- Vital signs and fetal monitoring during your labor

The following are for research purposes only. This means you will only have these if you agree to be in the study:

- **Screening/Randomization:** At 25 weeks 0 days to 34 weeks 0 days gestation you will be randomized to either the waterbirth or land birth group.
- **Questionnaires:** If you agree to participate in this study, you will receive a short questionnaire post-delivery, called *The US Birth Satisfaction Scale Revised* (US-BSS-R), asking how satisfied you were with your birth experience. You may skip any question that makes you uncomfortable. You may ask the research coordinator, midwives, or obstetricians, if you have any questions about the words used in this questionnaire.

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What will happen at each study visit?

Visit	During this visit, you will	How long is this visit?	Reminders
Visit 1 (Screening/Randomization)	• Have your usual third trimester prenatal labs drawn (25 weeks 0 days to 34 weeks 0 days gestation) • Review and sign this consent form first (may choose to consent at next prenatal visit if in inclusion window) • Be randomized to either the waterbirth group or the land birth (normal care) group once consented • Have your usual prenatal checkup •	1.5 hours Including your prenatal visit	Schedule your remaining prenatal visits
Visit 2 (Delivery and hospital stay)	• Undergo waterbirth or land birth based on randomization and eligibility • Answer a short questionnaire about your birth experience	Unknown; 20 minutes for questionnaire	All are completed while you're in the hospital
Visit 3 (Postpartum)	• At approximately 4-8 weeks postpartum, someone from the study will try to follow up with you regarding newborn status	10 minutes	Your participation in this study is completed

Are there any risks to me?

There may be risks, side effects, and discomforts if you choose to participate in this study. These can be physical, emotional, financial, or social. The ones we know about are listed below.

Maternal risks: infection and all risks associated with any vaginal delivery including but not limited to hemorrhage (extra bleeding), laceration (vaginal tearing), sepsis, and other rare maternal morbidity and mortality. Additionally, although rare, there is risk of falling while getting out of the tub.

Neonatal risks: all risks associated with any vaginal delivery including but not limited to infection, sepsis, water inhalation, umbilical cord avulsion (tearing), respiratory distress, low APGAR scores, NICU admission, and rare adverse neonatal morbidity and mortality including neonatal death.

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All maternal and neonatal risks will be discussed with you prior to consent and throughout your pregnancy. **Ultimately, Waterbirth is considered by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) to be an experimental procedure and, therefore, not all risks and benefits are known.** This study is being done to try to find out what the risks and benefits of waterbirth are. Waterbirth is considered an option for low-risk healthy women by the American College of Nurse Midwives and the Royal College of Obstetricians and Gynecologists/Royal College of Midwives.

Questionnaire risks: You will complete a questionnaire in this study. Sometimes the questions can make people uncomfortable or bring back bad memories. You may skip any question that makes you uncomfortable.

Are there any benefits to me?
You may or may not benefit from being in this study.

If randomized to the waterbirth maternal benefits may include: improved pain control, fewer obstetric lacerations, increased comfort during labor, increased mobility, and ease of delivery positioning due to increased buoyancy, improved relaxation, a more satisfying birth experience, increased perception of control, decreased cesarean delivery, and an additional option for pain control in a hospital setting in the Milwaukee area.

If randomized to the waterbirth neonatal benefits may include: less exposure to maternal pain medication/narcotic use, fewer interventions in labor, fewer instrumental and cesarean deliveries, immediate skin-to-skin contact with improved infant maternal bonding, and fewer NICU admissions.

Again, waterbirth is considered by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) to be an experimental procedure and, therefore, not all risks and benefits are known. It is considered a beneficial option for low-risk healthy women by the American College of Nurse Midwives and the Royal College of Obstetricians and Gynecologists/Royal College of Midwives.

If you are randomized to the land birth you will not benefit from being in this research study. However, we hope the information we learn will help others in the future.

How much will it cost to participate?
In this study, you or your insurance will have to pay for all prenatal care, labor and birth care, and post birth care as usual. There is no additional charge for water birth.

Will I be paid to participate?
You will not be paid to participate in this study.

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How long will I be in the study?
You will be in the study for about 4-6 months, from the time you are approximately 28 weeks pregnant (enrollment can occur between 25 weeks 0 days to 24 weeks 0 days gestation), you give birth to your baby and are discharged from the hospital, and until you are 4-8 weeks postpartum.

The study may be stopped early by Advocate Aurora Health or the investigator. You could be asked to stop being in the study for any of the following reasons:

- for your safety
- if you do not follow our directions for this study

Do I have to be in this study?
You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your regular medical care.

As an alternative to participation you will have a land birth.

You may decide to participate now but change your mind and withdraw from the study anytime without penalty or loss of benefits. If you decide to withdraw before the last study visit, let the investigator know. There may be special procedures to follow for your safety.

What if I am or baby is harmed from being in the study?
If you or your baby get hurt or sick from being in this study, you should seek medical treatment as needed. Be sure to tell the investigator as soon as possible. We will bill your insurance, if you have any, and you will have to pay your usual copays or deductibles. If you have Medicare, we may send information that identifies you to Medicare. If you do not have insurance or if your insurance does not cover your treatment, we will bill you for the costs of the treatment.

Will my records be kept confidential?
Your study records will be kept as confidential as possible. You can find out more in the section "Information about Confidentiality and HIPAA Authorization."

What if there is new information about this study?
If we learn any new information about this study that might make you change your mind about participating, we will tell you.

If you want to know the results of the study once it is over, you can ask the investigator.

Who oversees this study?
The Advocate Aurora Health Institutional Review Board (IRB) has approved this study. The IRB is a group of people who review all research studies at Advocate Aurora Health to check that they meet federal laws and ethical standards.

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IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends and personal doctor before you decide.

Who do I contact?

If …	**You should contact**	**Contact information**
You are harmed by the research	Emily Malloy, CNM, APNP Or Advocate Aurora Health IRB office	[redacted] [redacted] (outside Milwaukee: [redacted])
You have questions about your rights as a research subject	Advocate Aurora Health IRB office	[redacted] (outside Milwaukee: [redacted])
You have questions, problems, concerns, information, input or complaints about this research study	Emily Malloy, CNM, APNP or Advocate Aurora Health IRB office	[redacted] or [redacted] (outside Milwaukee: [redacted])

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Information about Confidentiality and HIPAA Authorization

Note: In this authorization document, "you" and "your data" refer to the subject. If you are a parent or guardian, please remember that "you" refers to the study subject.

Federal law provides additional protections of you and your child's medical records and related health information. That law is the *Health Insurance Portability and Accountability Act* (HIPAA). This study's HIPAA statement is provided below. You are providing your authorization if you sign this form and the accompanying consent or permission form to participate in the study.

Who will see my or my baby's protected health information?

Who may have access to my information:	**Purpose:**
Advocate Aurora Health consultants and employees, including IRB members.	To protect the rights and safety of subjects and make sure the study information is correct.
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries).	To make sure applicable laws are being followed.
Organizations that grant accreditation to hospitals and research programs.	For Advocate Aurora Health to remain accredited.

By signing this form, you are authorizing access to and sharing of personally identifiable health information for you and your child. This includes direct access to you and your child's medical records at Advocate Aurora Health.

Please note that the study doctor or study staff may also share personal information about you if required by law (for example, if the study doctor or study staff suspects that you are going to harm someone or yourself; reporting of communicable disease (HIV, hepatitis, tuberculosis, etc.). If you have questions about this, please ask the study doctor.

How will my information be used for this study?

This section explains who will use and share you and your child's health information if you agree to be in this study. You must authorize this use and sharing of you and your child's information by signing this form or you cannot be in the study.

The study principal investigator and study staff will collect, use, and share identifiable health information about you and your child for the following reasons:

- to conduct this research study;
- to review the study, and to check the safety and results of the study;
- to seek government approval of an investigational study drug, vaccine, device or product if such was involved in the trial;

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- to assist a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Information used and shared may include:

- information from you and your child's medical records related to the research or your routine medical care;
- information collected about you and your child during the research and any follow-up related to study visits, tests, procedures, outcomes, etc.

The collected information may contain your name, address, telephone number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

How will my information be kept confidential?

We will keep you and your child's personal health information as confidential as possible. You and your child's identity will be protected as required by law and according to any policies described in the study consent form you were given. Researchers may share you and your child's information with representatives and agents of the sponsor(s) for the purposes of managing and overseeing the study. Usually the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead initials and a code number are used. Some personal information, such as date of birth, will usually be included but will not be used to identify you or your child.

Once you or your child's information leaves Advocate Aurora Health we cannot control how it is used, and the law may not require outside organizations to protect the privacy of your information.

If this study is designed so that you are intentionally not told what treatment or study intervention you are receiving (called a blinded study), you will not have access to health information in your medical record that was collected as part of this study until those who run the study determine it is no longer necessary to keep you blinded. This usually occurs after everyone in the study has completed study treatment or intervention but can sometimes last until all study data is collected and analyzed.

How do I cancel my authorization?

You can cancel your authorization to use and share you and your child's information at any time by writing a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and still remain in the main study.

If you cancel your authorization, no new information will be collected without your permission. The study doctor and study staff will still be able to use and share you and your child's information that has already been collected to maintain the integrity of the study.

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When will my authorization expire?

This authorization to use and share you and your child's information expires at the end of the research study when data analysis is complete, and study records have been destroyed.

If study information is used for scientific publications or educational purposes, all identifying information will be removed.

You will receive a signed and dated copy of this form for your records.

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.

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Subject name: _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.

_____

Subject signature Date Time

_____

Witness signature (if applicable*) Date Time

**Use when the subject cannot read the consent (for example, subject is blind, illiterate, or does not speak English). The witness must be present for the entire consent discussion. The witness signature means that the information in this document was presented to the subject, and the subject appeared to understand it.*

Parent name: _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to let my child be in the research study described above.
- I will receive a copy of this permission form after I sign it. A copy will be put in my child's medical record and/or study record.
- I am not giving up any legal rights by signing this form.

_____

Parent signature Date

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For Site Use only:

My signature below certifies the following:

- The subject has been given enough time and an adequate place to read and review this form.
- All elements of the study, as contained in this document, were explained, and discussed with the subject or his/her legally authorized representative **before** research-related procedures began.
- The subject has had a chance to ask questions and receive answers about this study.
- The subject expressed understanding of the study.
- The subject/LAR will receive a copy of the signed and dated consent form/authorization.

Name of person obtaining informed consent (print) Title Phone number

Signature of person obtaining informed consent Date Time

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Risk/Benefit/Alternatives Discussion

I have explained and discussed with the subject or his/her legally authorized representative

- The nature of the research
- Potential risks and benefits
- The alternate treatments available to the subject and the benefits and risks of each

Name of person providing this information (print) Title

Signature of person providing this information Date

FILE A SIGNED COPY OF THIS FORM IN THE PATIENT'S MEDICAL RECORD (if applicable).
Keep the original in the investigator's research records.
Form IC 701A v. 2.8.19

THIS PAGE IS FOR DOCUMENTATION ONLY. IF GIVEN TO SUBJECTS, IT MAY BE BLANK**.**