

STANDARD CONSENT FORM

TITLE: The pilot PARTUM trial: A pilot study assessing the feasibility of a randomized controlled trial evaluating aspirin in postpartum women at risk of developing venous thromboembolism

SPONSOR: University of Calgary

# PRINCIPAL INVESTIGATOR: Leslie Skeith, Telephone: 403-944-5246

This consent form is only part of the informed consent process. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand all information given to you. You will receive a copy of this form for your records

## BACKGROUND

You are being asked to take part in this research study because you are pregnant or postpartum and have risk factors for blood clots. Some women are at risk for developing blood clots in the legs or lungs (thrombosis) after they deliver a baby. The risk of blood clots is highest in the first 6 weeks after delivery. While we can identify what these risk factors are, we still don’t know what the best way is to prevent blood clots. Previous research studies tried to see if using daily injectable blood thinners after having a baby could prevent blood clots. This study was not successful because taking daily injectable blood thinners at home was not very popular. Most women who deliver in Calgary who have risk factors for blood clots may be given injectable blood thinners while they are in hospital, but they usually do not go home on injectable blood thinners.

Could there be an alternative to taking injectable blood thinners at home? Aspirin helps to prevent blood clots in people after hip and knee surgery. We are studying whether aspirin will help to prevent blood clots in postpartum women with risk factors for blood clots.

## WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this research study is to see if we can recruit enough women to make a larger study possible. We will collect information about blood clots and bleeding that will be used in the larger research study to see if aspirin can safely prevent blood clots in postpartum women at risk of blood clots. This will allow us to better care for postpartum women who are at risk of blood clots.

## WHAT WOULD I HAVE TO DO?

If you choose to take part, after the birth of your baby you will be given aspirin 81 mg or placebo pills (sugar pills) every day for 6 weeks. Before you leave the hospital, we will give you a bottle of the medication (aspirin or placebo) to take every day for 6 weeks. No blood work or imaging tests are needed for the study.

If your doctor thinks you are at a high risk for developing blood clots and they recommend that you go home on injectable blood thinners, or you need aspirin for other reasons, then you are not eligible to participate in this study.

Participants and their doctors will not know what treatment they receive. A computer system is used to randomly put each participant in either the aspirin or placebo group. The doctors and research team do not get to choose or know which medication you will be given. You will not know if you are taking the aspirin or the placebo medication. If an emergency arises and your doctor needs the information, they will be able to know if you have been given aspirin or placebo.

After 6 weeks of taking the study medication every day, we will contact you to ask you questions that will take 15 minutes or less to answer. The questions will be about symptoms of blood clots, bleeding and possible side effects. This 6-week visit can be in person or by a telephone or video call. We will ask you similar questions at 3 months by a telephone call. We are available over the telephone or in person if you have any questions or new symptoms that come up any time within the 3-month study duration.

We will ask you to keep a simple checklist to track any days that you missed taking the study medication. At the 6-week visit we will ask for your checklist and your medication bottle back. If you chose to complete the 6-week visit by phone or video call, then we will provide you with a pre-paid envelope to mail the empty medication bottle back.

We estimate that 336 participants will be in our research study in 7 centres around the world, and 48 participants will be from Calgary.

## WHAT ARE THE RISKS?

Low dose aspirin is well tolerated. Side effects of aspirin at low doses include nausea, stomach upset and a small increased risk of bruising or bleeding, including gastrointestinal (stomach and intestines) bleeding. There is the potential that aspirin could make your lochia (vaginal bleeding after birth) heavier. Aspirin can trigger asthma, bronchospasm (tightening of the muscles that line the airways) or allergic reactions, especially in those already at risk (people who have asthma, hay fever, nasal polyps or chronic lung disease). If you are in the group that is given the placebo medication, you may not benefit from the medication so you could be at a small risk of developing a blood clot.

There is a risk of a privacy or confidentiality breach, but we will take every precaution to protect your personal information. We will only collect and use the minimal amount of information needed to answer our research questions.

## ARE THERE ANY RISKS WITH BREAST FEEDING?

Expert guidelines recommend that low doses of aspirin can safely be taken daily during breast feeding, but that higher doses of aspirin should be avoided. In this study, we will be using a low dose of aspirin and we recommend taking only one pill of the study medication every day. Low dose aspirin is safe to babies who are being breastfed.

In a research study of women who took aspirin 81 mg daily, there was no aspirin detected in breast milk. Only a small amount of the break-down products of aspirin was detected in breast milk and that amount was below the level considered safe for breast-fed infants. In a research study of postpartum women who were taking low doses of aspirin, there were no negative effects seen in their breast-fed babies.

## WILL I BENEFIT IF I TAKE PART?

If you agree to take part in this study there may or may not be a direct benefit to you. Your chance of developing a blood clot after delivery of your baby may improve during the study but there is no guarantee that this research will help you. The information we get from this study may help us to provide better treatments in the future for women at risk of blood clots after delivering a baby.

If you decide to take part in this study you will be given information to help you be aware of the signs and symptoms of a blood clot. This information as well as discussions with study doctors could help you to detect potential blood clots. You will be given contact information for the study team so that you can reach out at any time to ask questions about the research study. The study team and doctors are available to discuss any concerns or symptoms you are experiencing.

## DO I HAVE TO TAKE PART?

Your participation in this study is voluntary. The alternative to this study is not to take part. There is currently no standard or approved treatment available, but you can talk to your doctor about two different options available. The options include going home on no preventative medication for blood clots or on injectable blood thinners.

It will not affect your medical care if you decide not to be in this study, or to be in the study now, and then change your mind later. If your health changes, then your doctor may also withdraw you from the study at any time.

If you withdraw your consent, the study team will no longer collect your personal or health information.

If new information becomes available that might affect your participation in the study, then you will be informed as soon as possible.

## WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

You will not receive any money for participating in the study. We will reimburse you for your parking for the 6-week study visit, if you choose to attend this visit in person.

## WILL MY RECORDS BE KEPT PRIVATE?

We will protect your confidentiality.

* All information collected during your participation in this study will be given a unique study number, and will not contain information that identifies you, such as your name, address, etc.
* The link between your unique study number and your name and contact information will be stored securely and separate from your study records and will not leave an Alberta Health Services facility.
* Any documents leaving an Alberta Health Services facility will contain only your unique study number. This includes publications or presentations resulting from this study.
* Information that identifies you will be released only if it is required by law.
* Research records will be kept for 25 years by law, after this time they will be destroyed.

If you agree to join this study, we may need to access your personal health records. Any personal health information that we get from these records will be only what is needed for the study. This may include accessing records with Alberta Health Services and/or your electronic health record in Netcare, the provincial electronic health record system.

A description of this clinical trial will be available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov). 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.

Authorized representatives from the University of Calgary, the Conjoint Health Research Ethics Board and Health Canada may look at your medical study records that include your personal information for quality assurance purposes.

Data collected during your time in this research study will have your personal information removed. This data will be held in a database for future use for the larger PARTUM research study. Any future use of this research data is required to undergo review by a Research Ethics Board.

## IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the event that you suffer injury as a result of taking part in this study, no compensation will be provided to you by the University of Calgary, Alberta Health Services or the Researchers. You still have all your legal rights. Nothing in this consent form changes your right to seek damages.

## SIGNATURES

Your signature on this form means that you have understood the information about your participation in the research project and agree to take part. In no way does this remove your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without affecting your health care. If you have further questions about this research, please contact:

Dr. Leslie Skeith, (403) 944-5246

If you have any questions about your rights as a possible participant in this study, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

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| Participant’s Name |  | Signature and Date |
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| Investigator/Delegate’s Name |  | Signature and Date |
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| Witness’ Name |  | Signature and Date |
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The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.