Sinai Health | Mount Sinai Hospital
Joseph & Wolf Lebovic Health Complex

# CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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| **Title** | Low Molecular Weight hEparin vs. Aspirin Post-partum (LEAP) |
| **Investigators** | Drs. Evangelia Vlachodimitropoulou, Kellie Murphy, Nadine Shehata, Eric Kaplovitch, Ann Kinga Malinowski |
| **24 Hour Phone Number** | 416 -596-4200 |
| **Sponsor** | Division of Hematology, University of Toronto |

## Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

## Background and Purpose

- You are being asked to take part in this research study because of your risk of developing a blood clot after delivering your baby. Blood clots are gel-like clumps of blood that block blood vessels. The clots can be in your leg and or in your lungs. Your risk is roughly estimated to be 6.5%
- The usual treatment to help prevent blood clots is injections of a blood thinner called low molecular weight heparin (LMWH) for 6 weeks, starting on the first day after the delivery of your baby.
- The problem with this treatment is that it has to be administered using daily injections under the skin which can be painful and can cause bleeding. The medication is also costly and it is not known whether 6 weeks of treatment is necessary.
- This study will look at using 3 weeks of LMWH followed by 3 weeks of an Aspirin tablet taken orally once a day compared to 6 weeks of LMWH treatment.

- Both LMWH and Aspirin have been safely used to prevent blood clots such as after knee replacement surgery but not after pregnancy. This is why our study is considered experimental.
- About 50 people from Mount Sinai Hospital will be in the study. This is a pilot study to see if patients are willing to accept either 6 weeks of LMWH or 3 weeks of LMWH and 3 weeks of aspirin. This will help the investigators design a larger study. The purpose of the larger study is to ensure that women are receiving the treatment to prevent blood clots that reduces their chances of getting a blood clot and their risk of bleeding.

## Study Design

- This study compares 6 weeks of treatment with LMWH injections with 3 weeks of LMWH injections followed by 3 weeks of oral Aspirin following the delivery of your baby.

- Which treatment you get will be decided randomly (by chance), in a 1:1 ratio as per protocol. The number of people in each group will be 25.

- This study will not be blinded. This means that you will be told right after delivery which group you have been allocated to.

- You will be in this study receiving treatment for 6 weeks, but you will have your final telephone follow-up at 3 months.

- There will be 3 telephone follow-up visits. Most visits will last at the most, 20 minutes.

## Study Visits and Procedures

### *Screening*

- This visit will take place during one of your routine appointments at the Special Pregnancy Program clinic at Mount Sinai Hospital. It will take approximately 20 minutes, and the study will be explained to you by a member of our team. We will also record a list of your medications and your weight, which will have been placed in your hospital chart.

### *Dosing*

- After you delivery, you will take your treatment prescription to the pharmacy in order to collect your medication. The prescription will reflect which treatment group you

were allocated to. The prescription will have been given to you during a routine clinic appointment or by a team member who will visit you after delivery.

- You will receive a phone call at 3 weeks, 6 weeks and 3 months after you delivery that will last approximately 20 minutes. We will ask you about any changes to your medications and if you have had any issues with bleeding complications or blood clots. Also, we will note your compliance with the medication and ask you questions regarding your quality of life at the time of treatment.

- **Randomization**: You will be given a medication prescription during a routine clinic appointment or right after delivery, which will let you know which treatment group you have been assigned to.

**Calendar of Visits**

**Boxes marked with an X show what will happen at each visit:**

| **Participant** | **Screening**<br><br>Week -8 to Day -1 | **Dosing**<br><br>Day 1 | **3-week phone call**<br><br>± 5 days | **6-week phone call (end of study medication)**<br><br>± 5 days | **3-month phone call**<br><br>± 5 days | **Early Disconitu ation Visit** |
|---|---|---|---|---|---|---|
| Consent | X | --- | --- | --- | --- | --- |
| Baseline demographics | X | --- | --- | --- | --- | --- |
| Weight/BMI | X | X | X | X | X | X |
| Concurrent medications | X | --- | X | X | X | X |
| Delivery Data: Type of delivery/ complications | --- | X | --- | --- | --- | --- |
| Laboratory Data: Complete blood count/ Creatinine/ INR/ aPTT/ ALT | --- | X | --- | --- | --- | --- |
| Drug dispensation | --- | X | --- | --- | --- | --- |
| Compliance assessment | --- | --- | X | X | --- | X |
| Quality of life assessment | --- | --- | X | X | --- | X |
| Bleeding assessment | --- | --- | X | X | --- | X |
| Time | 20 mins | 20 mins | 20 mins | 20 mins | 20 mins | 20 mins |

## Reminders

It is important to remember the following during this study:

- It is important to take your medication.
- Ask your study team about anything that worries you.
- Tell study staff anything about your health that has changed such as leg swelling, chest pain or shortness of breath.
- Tell your study team if you change your mind about being in this study.

## Risks Related to Being in the Study

This study has risks. Some of these risks we know about. There is also a possibility of risks that we do not know about and have not been seen in study subjects to date. Please call the study doctor if you have any side effects even if you do not think it has anything to do with this study. The risks we know of are:

The risk of developing a clot after pregnancy is 6.5%. This risk is reduced to 1.8% with LMWH. If you are randomized to the Aspirin group, it is possible that your risk of developing a clot may be different than if you were taking LMWH for the full 6 weeks.

LMWH is associated with 10% risk of minor bleeding, 1.8% risk of skin reactions, wound separation (6.8%), wound hematoma (swelling with clotted blood) (1.7%) rehospitalization (2.1%) after cesarean delivery.

Aspirin was not associated with increased bleeding complications and gastrointestinal bleeding compared to no treatment when used for prolonged periods during pregnancy. Aspirin was associated with a similar rate of risk of blood clotting after knee surgery, approximately 0.7%.

## Risks Related to Pregnancy

If you do get pregnant again while taking LMWH or Aspirin, this is not harmful and does not affect an unborn baby. You should tell the study doctor if you are pregnant again during the time period of the study.

## Risks Related to Breastfeeding

Both LMWH and Aspirin can be used with breastfeeding.

## Benefits to Being in the Study

You may or may not receive direct benefit from being in this study. Information learned from this study may help other people with an increased risk of developing blood clots during the postpartum period in the future.

You may find it beneficial if you are allocated to the group treated with 3 weeks of LMWH followed by 3 weeks of Aspirin that you have to inject yourself for 3 fewer weeks, as this is less painful and not as costly.

**Incidental Findings**

Tests conducted for the study are not for the purpose of diagnosis, and results will not be reviewed by a doctor, or recorded in your medical history. However, a potential risk of participating in research is that investigators may discover an abnormality that may impact on your health. If warranted, a physician will meet with you to discuss the findings and a recommend a course of action.

**Voluntary Participation**

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time. If you choose to leave the study during the first 6 weeks after delivery of your baby, you will receive the standard clinical treatment which is LMWH for a total of 6 weeks after delivery. You may refuse to answer any question you do not want to answer, or not answer an interview question by saying “pass”.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

**Alternatives to Being in the Study**

If you do not wish to participate in the study you will be advised to follow the standard treatment with 6 weeks of LMWH injections after the delivery of your baby.

**Confidentiality**

Personal Health Information

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name,
- new or existing medical records, that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 10 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- The study sponsor or its representatives/partner companies.
- Representatives of the Mount Sinai Hospital Research Ethics Board.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law.

You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

Email is not a secure form of communication and should not be used for conveying sensitive information, or in the event of an emergency.

**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.

**In Case You Are Harmed in the Study**

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

**Expenses Associated with Participating in the Study**

If you are allocated to the group due to receive Aspirin, this will be provided free of charge.

**Conflict of Interest**

University of Toronto, Division of Hematology the sponsor of this study, will pay the hospital and researcher for the costs of doing this study. All of these people have an interest in completing this study. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this study.

**Communication with Your Family Doctor**

Your family doctor may be informed that you are taking part in this study so that your study doctor and family doctor can help you make informed decisions about your medical care.

**Questions About the Study**

If you have any questions, concerns or would like to speak to the study team for any reason, please call Dr. Shehata or Dr. Murphy at 416 596 4200 or email at Leap.Trial@sinaihealth.ca.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics Office number at 416-586-4875. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

**Consent**

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study {and to the use of my personal health information as described above}.

| _____ | _____ | _____ |
|---|---|---|
| Print Study Participant's Name | Signature | Date |

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

| _____ | _____ | _____ |
|---|---|---|
| Print Name of Person Obtaining Consent | Signature | Date |