2021

Preventing Adverse Incisional Outcomes at Cesarean Multicenter Trial

PREVENA – NCT03009110

INFORMED CONSENT

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Prophylactic Negative Pressure Wound Therapy in Obese Women at Cesarean: a Multicenter Randomized Trial
Sponsor: The National Institute of Child Health and Human Development (NICHD/NIH)
IRB: 1805526738

About this research
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

The study is being conducted by Dr. Methodius Tuuli and Indiana University. It is funded by the National Institute of Child Health and Human Development, which is part of the National Institutes of Health (NIH).

Taking part in this research study is voluntary
You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with your physician, hospital or Indiana University.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. **Why is this study being done?**
   The purpose of this research study is to lower rates of surgical site infections in women with a body mass index (BMI) greater than or equal to 30 pre-pregnancy after undergoing a cesarean delivery. For more information, please see the *Why is this Study being Done* section below.

2. **What will happen to me during the study?**
   You will be randomized, like flipping a coin, to one of two groups. One group will receive the standard abdominal pressure dressing following your C-section and the other group will receive the Prevena device. Additionally, there are optional biospecimen collections. For more information, please see the *What Will Happen during the Study* section below.

3. **How long will I participate?**
   You will be participate from the time of consent through approximately 6 to 8 weeks after your delivery.

4. **Will I benefit from the study?**
   It is possible that you may benefit from taking part in this study; however, there is no guarantee that it will help you. For more information, please see the *What are the Potential Benefits of Taking Part in the Study* section below.

5. **Will taking part expose me to risks?**

Taking part in this research may expose you to significant risks. It is very important that you understand the risks before you decide whether to participate. Some of the most common risks include: skin blisters, redness, wound bleeding or prolonged wound drainage. For more details, please see the *What Are the Risks of Taking Part in the Study* section below.

6. **Do I have other options besides taking part in this study?**
   There may be other options for treatment of your C-section incision, including creating a treatment plan with your doctor. For more details, please see the *What are the Other Treatment Options* section below.

7. **Will I be paid to participate?**
   Payment for your time is available if you decide to take part in this study. For more information, please see the *Will I be Paid for Participation* section below.

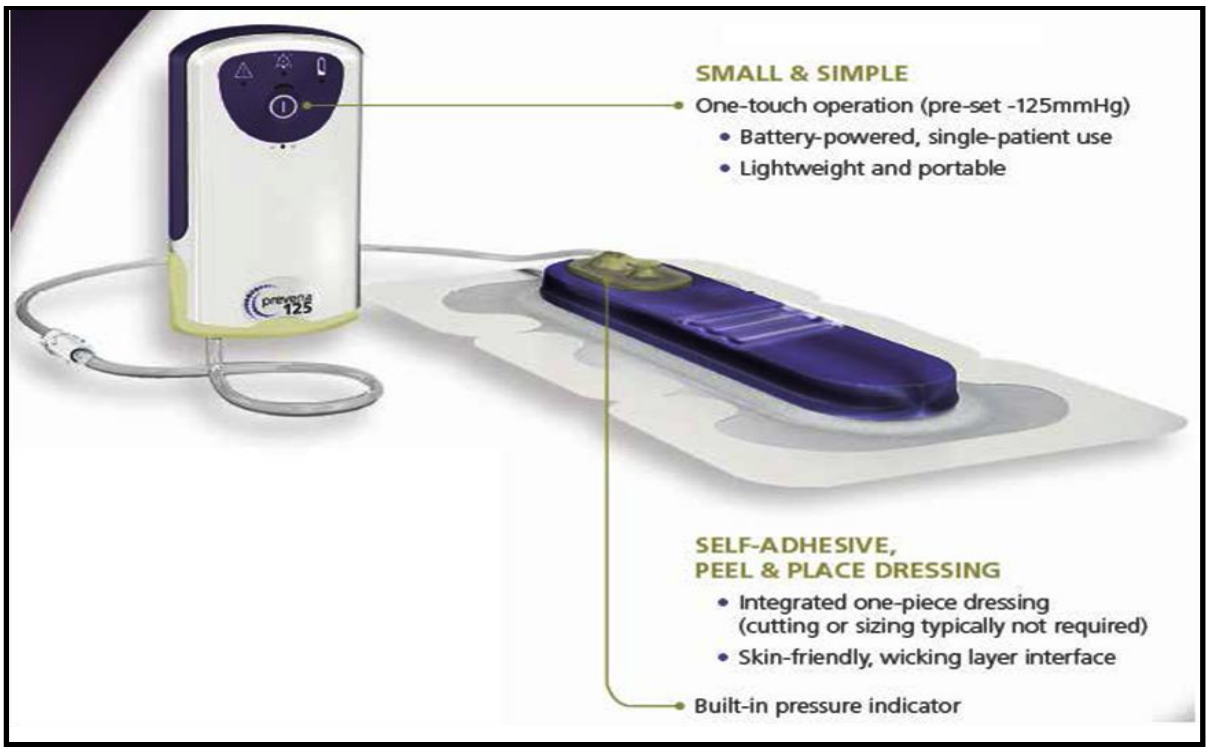
8. **Will it cost me anything to participate?**
   You will not be responsible for any costs related to the research; however, you or your insurance company will still be responsible for the cost of your normal medical care.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this study.

WHY IS THIS STUDY BEING DONE?
We invite you to participate in this research study because you are a pregnant woman with a pre-pregnancy (before you were pregnant) body mass index (BMI is a calculation of your height and weight) greater than or equal to 30 and are undergoing a cesarean section.

The purpose of this research study is to lower rates of surgical site infections in women with a BMI greater than or equal to 30 pre-pregnancy after undergoing a cesarean delivery. We are looking to see how effective it would be to prevent any complications by applying a Negative Pressure Wound Therapy device to the incision immediately after surgery to help promote wound healing. The Negative Pressure Wound Therapy device is composed of a vacuum pump, drainage tubing, foam or gauze wound dressing and an adhesive film dressing that covers and seals the wound.

The PREVENA Negative Pressure Wound Therapy device is a very small lightweight, portable suction device (like a vacuum) that is approved by the U.S. Food and Drug Administration to help promote wound healing by removing any moisture on the incision.



HOW MANY PEOPLE WILL PARTICIPATE?
Approximately 500 people will take part in this study conducted by investigators at Indiana University. A total of 2850 women will take part in this study across all sites.

WHAT WILL HAPPEN DURING THIS STUDY?

- If you are eligible for the study we will go through the consent form and have you sign it. We will also have you sign a form authorizing the release of your health information for research. You will receive a copy of both forms.
- We will obtain your pre-pregnancy height and weight to accurately determine your Body Mass Index (BMI). You will then be randomized (like flipping a coin) to one of two groups in the study. One group will continue with their normal standard of care for their postoperative (after surgery) hospitalization

and the second group will have the Negative Pressure Wound Therapy device applied immediately after cesarean instead of the standard dressing. This is a silicone (like jelly) dressing that is placed over the incision with strips of tape called Tegaderm. The standard dressing is removed on postoperative day 1 and the Negative Pressure Wound Therapy device is removed right before you are discharged (usually postoperative day 3 or 4 but a maximum of 7 days).

- Optional Skin Swabs: Immediately before and 3 minutes after the skin is cleansed for surgery, two skin swabs will be taken across the lower abdomen, 2 inches above the pubic hair line where the incision will be made. These swabs will be cultured to see if there are any bacteria on the skin. We will also extract bacterial DNA (chemicals that provide instructions as to how the bacteria act in our bodies) from the swabs and use it to identify all of the bacteria in the skin or surgical wound. <u>This DNA study is of germs only</u>. We will not determine or study your DNA.
- Optional adipose tissue biopsy: During the cesarean delivery we ask to biopsy [take a small sample] the adipose (fat) tissue before the fascial (muscle) incision at the beginning of the cesarean delivery and also after the fascial (muscle) incision is closed at the end of the cesarean delivery. To do this your doctor would cut a small piece (about the size of a dime) of the adipose (fat) tissue with scissors. This adipose tissue will be stored for use in future studies.
- If you are discharged over the weekend when research staff is not available, we will contact you via phone within 48 hours post-discharge to assess for symptoms of surgical site infection as well as complete a pain assessment and your satisfaction with the dressing. You will be contacted via phone approximately 30 days after delivery to assess any symptoms of surgical site infections. You will be asked standardized questions regarding any wound complications. If you report any symptoms of surgical site infections, you will be directed to follow up in the emergency department or with your physician. If you are seen in the emergency room or physician's office for surgical site infection concerns we will request those records with a records release signed at enrollment. You may be contacted before 30 days if you have had any unscheduled visits to your doctor's office or visits to the emergency room.
- Your Medical records will be reviewed to obtain demographic, pregnancy, delivery and post-delivery information about you. If you are treated for a surgical site infection by your physician, your medical records will be obtained to determine the diagnosis, treatment and possible readmission within 6 weeks of cesarean delivery.
- Your infant's medical records will be reviewed and certain information will be obtained. These records will only be reviewed for information related from the time you deliver your baby until 6 weeks after delivery . For instance: gender, nursery status, weight, Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) scores, cord blood gas results, days in the neonatal intensive care unit (NICU, if applies), days on antibiotics (if applies) and a list of complications if applicable.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

<u>Negative Pressure Wound Therapy device</u>

Less Likely

- Skin blisters, erythema (redness), wound bleeding and prolonged (>7 days) wound drainage.

<u>Adipose Tissue Biopsy</u>

Less Likely

- Bleeding

Risks related to breach of patient confidentiality:
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THIS STUDY?
You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because reduction of surgical site infections is such a large problem with obese women.

WHAT ARE THE OTHER TREATMENT OPTIONS?
If you decide not to participate in this study, the standard of care at Indiana University is to place an abdominal pressure dressing following surgery and to remove it after 24 hours. There may also be additional incision dressing options; this should be discussed with your doctor.

WILL I RECEIVE MY RESULTS?
The samples will be stored for study tests. These tests will be run much later and used for research purposes. None of these test results will be placed in your medical record.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?
We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you;

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration (FDA).
- The National Institute of Child Health and Human Development.
- The National Institutes of Health (NIH).
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- Indiana University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Subjects Office. The Institutional Review Board has reviewed and approved this study.
- A data safety monitoring board or data coordinating center.

To help protect your confidentiality, we will store any paper documents in a double lock system (in a locked drawer behind a locked door). Any electronic data will be password protected and stored on a password protected computer or in a secure electronic database with a unique study ID number. The samples will be stored securely and labeled with a code that does not directly identify you. A list that links this code to your identifiers will be stored separately and available only to the study team. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly

identified.

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.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects
(4) for the purpose of auditing or program evaluation by the government or funding agency
(5) if required by the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

As part of this study, we are obtaining skin swabs (2), adipose tissue biopsies (2) and data from you. We would like to use these skin swabs, adipose tissue and date for studies going on right now as well as studies that will be conducted in the future. These studies may provide additional information that will be helpful in understanding surgical site infections or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your skin swabs, adipose tissue and data, you give up any property rights you may have in the skin swabs, adipose tissue and data.

We may use the specimens collected as part of this study for whole genome sequencing, which involves mapping all of your DNA.

We may share your skin swabs, adipose tissue and data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Indiana University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your skin swabs, adipose tissue and data for future research you should contact the research team member identified within this document. The skin

swabs, adipose tissue and data will no longer be used for research purposes. However, if some research with your skin swabs, adipose tissue and data has already been completed, the information from that research may still be used. Also, if the skin swabs, adipose tissue and data has been shared with other researchers it might not be possible to withdraw the skin swabs, adipose tissue and data to the extent it has been shared.

WILL I BE PAID FOR PARTICIPATING?
You will be paid for being in this research study. You will receive a $25.00 gift card prior to hospital discharge. If you decide that you do not want the dressing that you are assigned randomly to then you will not receive payment for participating.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
You will not be responsible for these study-specific costs: the Prevena device. The rest of your delivery care will be billed to your insurance provider and you/your insurance provider will be responsible for the cost of your care, just as you would be if you were not participating in the study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?
In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries at Indiana University. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHO IS FUNDING THIS STUDY?
The National Institute of Child Health and Human Development, which is part of the National Institutes of Health (NIH) is funding this research study. This means that Indiana University is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

The study is also receiving support from Acelity, which is the company that manufactures the PREVENA negative pressure wound therapy devices.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, contact the researcher, Dr. Methodius Tuuli, at 317-944-8182. If you cannot reach the researcher during regular business hours (i.e., 8 a.m. to 5 p.m.), please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu. After business hours, please call the on-call OBGYN physician where you have received your prenatal care.

In the event of an emergency, you may call 911 or go to the Emergency Department.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

IS BEING IN THIS STUDY VOLUNTARY?
Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your

participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

CAN I WITHDRAW FROM THE STUDY?
If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, please notify in writing: Dr. Methodius Tuuli, 550 University Blvd, Suite 2440, Indianapolis, IN 46202. You may also call 317-880-3949 to withdraw by phone.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study procedures.

PARTICIPANT'S CONSENT
In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____ **Date**:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____

OTHER CONSIDERATIONS

Please place your initials in the blank next to Yes or No for each of the questions below:

Do you agree to participate in the **optional** skin swabs?

_____ Yes **_____ No**
Initials **Initials**

Do you agree to participate in the **optional** adipose tissue biopsies?

_____ Yes **_____ No**
Initials **Initials**

Please place your initials in the blank next to Yes or No for each of the questions below:

My skin swabs, adipose tissue and data may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My skin swabs, adipose tissue and data may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes **_____ No**
Initials **Initials**