Northwell Health

Long Island Jewish Medical Center

Consent for Participation in a Research Study

Title: PICO negative pressure wound therapy in obese women undergoing elective cesarean delivery.

Principal Investigator: Anar Yukhayev, MD

Sponsor: Department of Obstetrics and Gynecology

About this research
You are being asked to participate in a research study.

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.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. 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.
Why is this research study being done?	The purpose of this study is to determine if there is a difference in surgical site (wound) complications and infection rates when a PICO negative pressure wound therapy dressing is used instead of the standard bandage in women who have an elective cesarean delivery and have a body mass index (BMI) of 35 kg/m^2 or greater.
What will happen to me during the study?	In this research study, you will be randomly assigned to get either the PICO device or the regular pressure dressing after your cesarean delivery. There will be no difference in the way that your cesarean delivery will be performed if you participate in this study. Study personnel will come to your room on the first day after your surgery and check your incision site (wound).

	If you assigned the PICO device, you will be given instructions on how to remove the PICO device on the fifth day after your surgery, and study personnel will call you to make sure you are above to remove the dressing accordingly and don't have any problems. If you are assigned the regular pressure dressing, your dressing will be removed as it usually is on the first or second day after your surgery. Your participation in the study does not require any additional visits, blood draws, or tests.
How long will I participate?	The study procedures will last for 5 days and you will be followed for another 42 days (routine care after a cesarean delivery). You will be asked to attend 2 visits (that are already part of your recommended post-operative care plan) that will last about 1 hour each for a period of 42 days.
Will taking part expose me to risks?	This study does not require you to have any extra procedures or treatments. Therefore, being in this study does not involve any risks that you would not face during your routine treatment, as some doctors already use the PICO dressing for cesarean deliveries. The first time the PICO pump is turned on, you may feel a slight pulling or drawing sensation. Also, the PICO pumps contain a magnet. Keep the PICO pumps at least 4 inches (10 cm) away from other medical devices at all times. As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices.
Are there any benefits to participation?	This research will not benefit you directly. However, the information we learn about this wound dressing may help other patients in the future.
What are my alternatives to participation?	If you do not join this study, you have other choices for treatment that will be at the discretion of your doctor. Some doctors already use the PICO dressing for cesarean deliveries and some do not. Talk to your doctor about your choices. Your other choices may include: • Standard treatment (a usual pressure dressing) • Treatment provided on this study (the PICO dressing)

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 research.

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions.

This consent form will explain:
- the purpose of the study
- what you will be asked to do
- the potential risks and benefits

It will also explain that you do not have to be in this study to receive medical care. You should ask questions before you decide to participate. You can also ask questions at any time during the study.

Why is this research study being done?
The purpose of this study is to determine if there is a difference in surgical site (wound) complications and infection rates when a PICO negative pressure wound therapy dressing is used instead of the standard bandage in women who have an elective cesarean delivery and have a body mass index (BMI) of 35 kg/m^2 or greater. You are being asked to participate in this study because you are having an elective cesarean delivery and you have a BMI of ≥ 35 kg/m^2.

How many people will take part in this study?
This research study will enroll approximately 396 patients.

How long will you be in this study?
If you choose to take part in this study, the study procedures will last for 5 days and you will be followed for another 42 days (routine care after a cesarean delivery). You will be asked to attend 2 visits (that are already part of your recommended post-operative care plan) that will last about 1 hour each for a period of 42 days.

What will happen in this research study?
The PICO Single Use Negative Pressure Wound Therapy Device (Smith and Nephew Healthcare, Hull, United Kingdom) is a non-significant-risk medical device commercially available in the USA and is already used in some cases for general surgery, gynecologic oncology and cesarean delivery incisions. In this research study, you will be randomly assigned to get either the PICO device or the regular pressure dressing after your cesarean delivery. There will be no difference in the way that your cesarean delivery will be performed if you participate in this study.

Study personnel will come to your room on the first day after your surgery and check your incision site (wound). You will be able to go home in the usual amount of time after your baby is born, and will be given instructions on how to remove the PICO device if you have one on the fifth day after your surgery. If you are picked to have the regular pressure dressing, your dressing will be removed as it usually is on the first or second day after your surgery.

If you have a PICO dressing as part of the study, study personnel will call you on the fifth day after your surgery to make sure you are able to remove the dressing accordingly and don't have any problems with the dressing.

Your doctor will see you in the clinic when you come for your regularly scheduled incision (wound) check two weeks after you are discharged from the hospital and your regularly

scheduled postpartum visit six weeks after you are discharged from the hospital. Your participation in this study does not require any additional visits after you are discharged from the hospital.

If you develop a fever, redness, pain, swelling, warmth, or drainage from your incision site after you go home, you will be instructed on whom to call for help and study personnel will also check on you.

Your participation in this study does not require any additional blood draws or tests.

What are the risks of the research study? What could go wrong?

Standard of Care/No Additional Expected Risk
Your participation in this research study is allowing the researcher to use data from your medical record. The tests and treatments you will receive are part of the standard of care for your condition. This study does not require you to have any extra procedures or treatments. Therefore, being in this study does not involve any risks that you would not face during your routine treatment, as some doctors already use the PICO dressing for cesarean deliveries.

The first time the PICO pump is turned on, you may feel a slight pulling or drawing sensation. Also, the PICO pumps contain a magnet. Keep the PICO pumps at least 4 inches (10 cm) away from other medical devices at all times. As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices.

What are the benefits of this research study?
This research will not benefit you directly. However, the information we learn about this wound dressing may help other patients in the future.

If you do not want to take part in this research study, what are your other choices?
If you do not join this study, you have other choices for treatment that will be at the discretion of your doctor. Some doctors already use the PICO dressing for cesarean deliveries and some do not. Talk to your doctor about your choices. Your other choices may include:

- Standard treatment (a usual pressure dressing)
- Treatment provided on this study (the PICO dressing)

Are there any costs for being in this research study?
This research study is funded by The Department of Obstetrics and Gynecology. You will not have any added costs from being in this study.

Will you receive any payments for participating in this research study?
You will not receive any payments for participating in this research study.

If the research produces marketable products, will you receive any payment?
If this research produces a marketable product, there are no plans for you to receive any money.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:
- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data or information will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

Investigators will share information collected from this research study with:

- study sponsor and/or its agents,
- clinical staff not involved in the study who may be involved in participant's treatment

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from Northwell Health's Human Research Protection Program (a group of people that oversee research at this institution)
- Representatives from Federal and state government oversight agencies, such as the Department of Health and Human Services, the Food and Drug Administration.

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish the results of this study in scientific journals and may present it at scientific meetings. If we do, you will not be identified.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Dr. Anar Yukhayev
Department of Obstetrics & Gynecology Long Island Jewish Medical Center 270-05 76th Ave, Suite MH G069
New Hyde Park, NY 11040

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?
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.

Will my information be used for research in the future?
Information collected from you or from your medical records for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your de-identified data to be used by future researchers without additional consent.

Does the investigator of this study receive money if you take part?
The investigators on this study do not receive money for your participation in this study.

Who can answer your questions about this study?
If you have any questions about the study, you may call Dr. Anar Yukhayev at (718) 470-7660. If you have questions about side effects or injury caused by research you should Dr. Anar Yukhayev at (718) 470-7660. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____ _____
Witness's Printed Name Witness's Signature Date
(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement
I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's signature **Date**

_____
Investigator's printed name