19-010500 (MC2061)

Wound Infiltration with Liposomal Bupivacaine with or without Intrathecal Analgesia in Laparotomy for Gynecological Malignancy: A Randomized Controlled Trial

NCT04258631

Document Date: 12/02/2022

MAYO CLINIC

Name and Clinic Number

Approval Date: **December 2, 2022**
Not to be used after: **December 1, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Wound Infiltration with Liposomal Bupivacaine with or without Intrathecal Analgesia in Laparotomy for Gynecological Malignancy: A Randomized Controlled Trial

IRB#: 19-010500

Principal Investigator: Dr. Sean Dowdy and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to compare two types of pain medication given in the operating room for women undergoing major abdominal surgery. One type of pain medication is infiltrated in the skin surrounding the abdominal incision. The other is given as an intrathecal (spinal) injection in combination with the first medication infiltrated into the skin near the abdominal incision. You have been asked to take part in this research because you are scheduled to undergo abdominal surgery for a suspected or diagnosed gynecological cancer.
What's Involved	Study participation involves your willingness to be randomized (like the flip of a coin) to receive either: 1) A standard pain medication which is infiltrated into the area surrounding your abdominal incision when your skin is surgically closed, or

	2) An intrathecal (spinal) injection of pain medication during surgery, in addition to a standard pain medication which is infiltrated into the area surrounding your abdominal incision when your skin is surgically closed. You will be asked to complete a short questionnaire before surgery and two short questionnaires approximately 24 hours after surgery. After finishing the questionnaires, your participation in this study will be complete. Your medical record will be reviewed for other information related to your surgery and hospitalization.
Key Information	All of the women enrolled in this study will receive the current standard medication infiltrated into the abdominal incision. Half of the women in this study will be assigned to receive an intrathecal (spinal) pain medication in addition to the standard incision medication. Possible risks with the spinal injection include puncture site bleeding, infection, hematoma (collection of blood within the tissue), or spinal headache. Benefits from participation in this research are not certain; however, you may experience improved pain control. All other surgical procedures, postoperative care, and pain management will be done as per current standard routine. There will not be additional study visits following your hospital stay.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Sean Dowdy, M.D. **Phone:** (507) 266-0225 **Study Team Contacts:** Karen Ishitani, R.N. **Phone:** (507) 538-5355 Maureen Lemens, R.N. **Phone:** (507) 293-1487 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
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.

Why are you being asked to take part in this research study?

You are being asked to participate in this research study because you are between ages 18 – 80 and you are scheduled to undergo an open abdominal surgery (laparotomy) for a suspected or diagnosed gynecological cancer.

The plan is to have about 104 women take part in this study at Mayo Clinic.

Why is this research study being done?

The purpose of this research is to gather information about the effectiveness of using two types of approved pain medication with the intent to provide improved pain control during the first postop day. Both medications are given during the surgical procedure. Liposomal bupivacaine is routinely infiltrated into the skin surrounding the abdominal incision and is effective in providing good relief of incisional pain. Intrathecal (spinal) hydromorphone, given as a single injection, will be used in this study as an additional medication with the intent to provide better management of deep abdominal pain during the first 24 hours postop.

Information you should know

Who is Funding the Study?

Mayo Clinic is providing funding for this study.

How long will you be in this research study?

You will be in this study until approximately 24 hours after your surgery. Your medical record will be reviewed later by the study team for information about your surgery and hospital stay.

What will happen to you while you are in this research study?

If you agree to participate in this study:

- You will be asked to complete a short questionnaire in the clinic before surgery.
- You will be asked about basic health and medical history.
- You will be randomized to one of two study groups (like the flip of a coin)
    - One group will be assigned to receive only the standard infiltration of medication in the abdominal incision at the end of the surgical procedure
    - The other group will be assigned to receive a single intrathecal (spinal) injection of pain medication in addition to the standard infiltration of medication in the abdominal incision at the end of the surgical procedure.
- Your surgical procedure will be performed as planned.
- Your postop care will be standard normal routine.
- Pain medications will be given as needed per the standard normal routine.
- Approximately 24 hours after your surgery, you will be asked to complete two short questionnaires

What are the possible risks or discomforts from being in this research study?

Your surgeon will discuss the risks of your scheduled surgery and any tests or procedures that are part of your standard clinical care.

The anesthesia staff will discuss the risks related to anesthesia and the risks related to intrathecal (spinal) injections if you are assigned to that group.

Possible risks related to spinal injection include puncture site bleeding, infection, hematoma, and spinal headache. Possible effects of systemic opioids include itching, nausea and vomiting, sedation, and respiratory depression. There is also a possible risk for delayed recovery. As with any medication, allergic reactions are possible.

If you think you might be pregnant, you must tell the study team immediately. You cannot be enrolled in this study if you are known to be pregnant.

With all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the study team if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you do not follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used. We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

This study may not make your health better. However, it is possible that you may have improved pain relief after surgery. Others undergoing similar abdominal surgery may benefit in the future from what we learn in this research study.

What alternative do you have if you choose not to participate in this research study?

You do not need to be in this study to receive treatment for your condition. Your other choices may include undergoing surgery without participating in the study.

What tests or procedures will you need to pay for if you take part in this research study?

There will not be additional charges to you for participating in this study. However, you and/or your insurance will need to pay for your surgery, anesthesia, hospital stay, all other tests and procedures that you will have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will not be paid for taking part in this study.

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Will your information or samples be used for future research?

Your information collected for this study will not be used or shared for future research studies even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. A unique study ID code will be assigned to you for this study. Your data including your questionnaires will be labeled with this code to protect your identity and maintain confidentiality. Data collected on paper will be kept in a locked research office. Data will be entered into a secure password-protected electronic database with access limited to the study team.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- The sponsor of this study and the people or groups hired by the sponsor to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature