Effect of Transversus Abdominal Plane Block Using Liposomal Bupivacaine Versus Standard Bupivacaine for Open Myomectomy: A Prospective Randomized Control Trial

PI: Daniel Katz
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STUDY INFORMATION:

Study Title: Effect of Transversus Abdominis Plane Block using Liposomal Bupivacaine versus Standard Bupivacaine on Quality of Recovery for Open Myomectomy: A Prospective Randomized Controlled Trial

Study site(s): Icahn School of Medicine at Mount Sinai,

Lead Researcher (Principal Investigator): Daniel Katz, M.D.

Physical Address: 5 East 98th Street, 2nd Floor, New York, NY 10029

Mailing Address: One Gustave L Levy Place Box 1170, NY, NY 10029

Phone: 212-241-7952

SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is improve the recovery process for participants who undergo abdominal surgery for the removal of uterine fibroids. Abdominal pain after surgery is detrimental to the recovery process, which causes prolonged immobility and more time in the hospital. Pain after surgery is currently treated with opioids through an IV or by mouth, which themselves cause unwanted side effects including constipation, decreased respiration, and long-term opioid use. To minimize the use of opioids, doctors use local anesthesia and nerve blocks as an alternative way of treating pain.

Bupivacaine is a long acting local anesthetic that is currently used in nerve blocks to provide long term pain relief. A newer preparation of this local anesthetic, called liposomal bupivacaine, is thought to provide superior pain relief compared to standard bupivacaine. The purpose of this study is to investigate the potential for liposomal bupivacaine to improve pain relief and thus enhance the recovery process for participant undergoing abdominal surgery for the removal of uterine fibroids.I

If you choose to participate, you will be asked to:

- Fill out a Quality of Recovery Survey before your surgery

- All participants will receive standard bupivacaine nerve blocks for prevention and treatment of pain, as is standard practice. Those who participate in the study may also receive liposomal bupivacaine in addition to standard bupivacaine
- Fill out a Quality of Recovery Survey 1 day and 2 days after your surgery
- Each survey is 15 questions and takes less than 3 minutes to complete

If you choose to take part, the main risks to you are:

- Allergic reaction - Participants will be monitored for signs of allergic reaction including hives, itching, flushing, swelling, dyspnea, wheezing, low blood pressure and fast heart rate. Allergic reaction will be addressed with immediate cessation of the liposomal bupivacaine or standard bupivacaine, administration of epinephrine, diphenhydramine, and steroids as clinically indicated, with escalation of supportive care as needed. These participants would be withdrawn from the study
- Local Anesthetic Systemic Toxicity (LAST) – While it is unlikely participants will experience toxicity given the planned dosing is well under reported toxic levels, participants will be monitored for signs and symptoms of LAST including but not limited to metallic taste, ringing in ears, nausea, vomiting, seizures, cardiac arrhythmias, and cardiovascular collapse. In the event of toxicity, the participant will be treated appropriately with an intralipid infusion, with escalation of supportive care as indicated. These participants would be withdrawn from the study

You will not benefit directly from taking part in this research. Others may not benefit either. However, possible benefits may be:

- Improved postoperative pain relief
- Decreased opioid use and thus decreased nausea, vomiting, and constipation
- Improved postoperative recovery with less overall recovery time and quicker return to work or usual home activities

Instead of taking part in this research, you may choose to opt-out and not receive a liposomal bupivacaine nerve block for postoperative pain relief. You will still receive the same standard of treatment for postoperative pain including standard bupivacaine nerve block and opioids administered IV and by mouth.

If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you have a diagnosis of uterine fibroids that can be removed surgically with an abdominal approach.

Your participation in this research study is expected to last 2 weeks, until you have recovered from your surgery.

There are 150 people expected to take part in this research study at Mount Sinai Health System

Funds for conducting this research study are provided by Mount Sinai Hospital

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

- You will meet with your gynecologist at Mount Sinai Hospital to schedule an appointment for surgery. During this office visit, your gynecologist will go through the consent form with you.
- During your initial office visit, before your surgery, you will be asked to complete a 15 question Quality of Recovery Survey to establish a baseline of your functional ability
- During surgery, your anesthesiologist will provide a nerve block with standard bupivacaine to provide postoperative pain relief, as is standard practice. You may or may not also receive liposomal bupivacaine as an experimental therapy as part of the nerve block. It is important to note that you may not receive liposomal bupivacaine even if you choose to participate in the study
- 24 hours after your surgery, you will be asked to complete the same 15 question Quality of Recovery Survey in order to assess the efficacy of the liposomal bupivacaine nerve block. Participants are normally discharged 1 day after surgery
- 48 hours after surgery, you will be asked to complete the same 15 question Quality of Recovery Survey for a third and final time. As participants are normally discharged 1 day after surgery, this questionnaire will be administered over the phone
- The duration of your participation will be throughout your hospitalization up until your first follow-up visit, for a total of about 2 weeks
- You will interact with doctors from the Department of Obstetrics & Gynecology, the Department of Anesthesiology, Perioperative & Pain Medicine, medical students from the Icahn School of Medicine of Mount Sinai, and nursing staff

- The research will be performed at the Mount Sinai Hospital beginning in the summer of 2019 up until the completion of the study
- Because this project involves the use of medications, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.
- The study treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what experimental study treatment you get. You will have a(n) equal one in two, or 50%, chance of being given each experimental treatment. Neither you nor the study doctor will know which experimental study treatment you are getting; however, this information could be obtained in an emergency

USE OF YOUR DATA AND/OR SAMPLES:

The research team will never use or share your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) that are collected as part of this study for future research, even if your identity is removed. Your data and/or samples will only be used to complete this study and then they will be destroyed.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:

- You will be asked to complete the 15-question Quality of Recovery Survey a total of three times:
  Once before your surgery, one day after your surgery and two days after your surgery

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for taking part in this study. Being in this study will not cost you anything extra. Researchers will not pay you for your travel or the time it will take for you to be in the study.

POSSIBLE BENEFITS:

There is a chance this study may benefit you, but this is not guaranteed. Others may benefit from what researchers learn from the study. Possible benefits to you include:

- Improved postoperative recovery and pain relief due to addition of liposomal bupivacaine to standard bupivacaine nerve block

POSSIBLE RISKS AND DISCOMFORTS:

- Rare chance of anaphylaxis, which is treatable but potentially irreversible and fatal
- Very rare change of arrhythmias resulting from local anesthetic systemic toxicity, which is treatable but potentially irreversible and fatal
- Bleeding, infection, or damage to surrounding structures at site of nerve block
  Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.
- In addition to these risks, this research may hurt you in ways that are not known. The unknown risks might be minor or might be major (death).

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

Instead of being in this research study, your choices may include:

- Receiving the standard treatment for postoperative pain including standard bupivacaine nerve block and opioids administered IV and by mouth.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form. If you are injured or made sick from taking part in this study, you will get medical care. The group funding this research study will pay you for any reasonable and necessary medical expenses to diagnose and treat research-related injury or illness. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

The Centers for Medicare and Medicaid Services (CMS) is the government agency that oversees Medicare and Medicaid. Funding agencies who make payments for injuries related to studies must

report payments to CMS. In order to do this, the funder must have certain information about you, such as your name, date of birth, Social Security Number, Medicare or Medicaid ID numbers, date of injury, and description of injury. The funding agency is only allowed to use this information to report payments related to the injury should this be necessary or as otherwise specified in the Authorization to Use and Disclose Protected Health Information section, which is included below.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number 212-241-7952

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DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?
As part of this research project, the research team at the hospital(s) involved in the research will collect your name, medical record number, dates of admission to hospital, dates of administration of Quality of Recovery surveys.
The researchers will also get information from your medical record from Mount Sinai Hospital

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)

- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, and temperature.
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).

In all disclosures outside of Mount Sinai, you will not be identified by [name, social security number, address, telephone number, or any other direct personal identifier] unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB)

allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI? :
Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will not be able to access your medical records. This is done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used

or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

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How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of Participant	Printed Name of Participant	Date	Time [required if used for FDA documentation purposes]

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of Witness	Printed Name of Witness	Date	Time