Evaluation of the Addition of Liposomal Bupivacaine to the Erector Spinae Plane (ESP) Block to Multilevel Lumbar Spinal Fusion Surgery
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STUDY INFORMATION:

Study Title: The Effect of Adding Liposomal Bupivacaine to Bilateral Ultrasound-Guided Erector Spinae Plane (ESP) Block to Multilevel Lumbar Spinal Fusion Surgery

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SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

PURPOSE OF THIS RESEARCH STUDY

The purpose of this research study is to determine if an injection near nerves in the back with a long-acting numbing medicine (local anesthetic) is more effective than a standard local anesthetic called bupivacaine currently used for nerve blocks in lumbar spine surgery. During lumbar spinal fusion surgeries, your anesthesiologist can perform an injection in the back called an erector spinae plane (ESP) block. This injection helps with postoperative pain in addition to standard pain medication (opioid medications such as morphine) during and after your procedure. We will perform the block after you are asleep and under general anesthesia. We will use an ultrasound machine to identify the area in your back that we want to block. We will then insert a needle and inject numbing medication in the target area. This medication will usually help with pain for 8-10 hours and can reduce the overall amount of intravenous (injection in to vein) and oral pain medications (opioids) that you might need.

Liposomal bupivacaine is a special form of bupivacaine developed relatively recently to last 24-72 hours. This medication has been approved by the FDA and used in a variety of injections safely and effectively. It is our goal to see if using this medication, instead of plain bupivacaine can be helpful in the setting of lumbar spinal fusion surgery as well. While regular bupivacaine works well to help alleviate pain after surgery for up to 24 hours, we want to see if we can extend that time even more by using liposomal bupivacaine. By giving some patients regular bupivacaine and some patients liposomal bupivacaine we will be able to directly compare if one medication is better.

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

- Receive an erector spinae plane block while under general anesthesia with either bupivacaine or liposomal bupivacaine.
- Answer a post operative questionnaire on pain, functional status (walking, movement, performing basic tasks like going to the bathroom), and use of pain medications on post operative days 1,2, and 3 as well as 2, 6 and 12 weeks post operatively via telephone.
- Receive a standardized treatment plan with regards to anesthesia and post operative pain. Should pain control not be adequate, this treatment plan can and will be altered to ensure adequate patient comfort and satisfaction.
- There will be no additional cost for these medications or injections.
- There will be no compensation to participate in this study.
- Your information will be confidentially stored within the Mount Sinai Health system.

The main risks to you if you choose to participate are bleeding, infection, damage to the surrounding tissue including but not limited to nerve and muscle damage. It is possible that this injection may cause an allergic reaction, a temporary drop in blood pressure, a temporary irregular heart rhythm or seizures. There is a risk that the injection may not be effective for pain control.

You may also benefit from participation in this research if the injection is effective as you will need less anesthesia, pain medication, and could possibly recover faster and go home sooner. Instead of participating in this research, you can choose to decline participation in the study but would not be denied an injection in the back for post operative pain control if you desire.
If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you are a relatively healthy adult individual undergoing lumbar spinal fusion surgery and you are not currently taking significant amounts of chronic pain medication.

Funds for the liposomal bupivacaine that may be used in this research study are provided by Pacira, the manufacturer of liposomal bupivacaine. The funding for conducting the research is otherwise provided by Mount Sinai.

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.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 12 weeks until the last post-operative questionnaire has been completed.
The number of people expected to take part in this research study at Mount Sinai Hospital is 84 people.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

- There are two study groups to which you may be assigned. Both groups will receive general anesthesia to fall asleep. The first group will receive the ESP block with the numbing medication bupivacaine. The second group will receive the ESP block with the longer acting numbing medication liposomal bupivacaine. The study treatment you get will be chose by a random computer generator. The chance of being in either group is like flipping a coin. Your study group assignment will be randomly chosen before your surgery. Neither you nor your study doctor will know what group you are in, however, this information could be obtained in an emergency.

- General anesthesia with or without a nerve block is commonly done for the surgery you are getting (lumbar spinal fusion). Both approaches are widely used at our hospital. Even if you were not part of the study, the anesthesia you would receive would be identical or very similar to one of these two approaches. While none of these approaches are investigational, we are conducting this study to see if the use of a longer acting numbing agent is superior to the current use of plain bupivacaine in controlling pain.

- If you were randomly assigned to be in group 1, you will receive a numbing medication called bupivacaine. The amount of local anesthetic medication will not exceed the accepted amount that should be given to patients.

- If you were randomly assigned to be in group 2, you will receive a numbing medicine called liposomal bupivacaine for your nerve block. You will not know which group you are randomized into.

- Your study involvement will begin on the day of your surgery. The beginning of surgery will proceed as it would for any lumbar spinal fusion surgery. You will get an intravenous line (IV) placed by your anesthesiologist either in the surgery waiting area or in the operating room. You will get medication through the IV to go to sleep. Once you are completely asleep, the anesthesiologist will place a breathing tube in your windpipe, which will be used to help you breathe during your surgery. Once the breathing tube is in place and you are positioned on your stomach for the surgery, the anesthesiologist will perform the ESP block with either plain

bupivacaine or liposomal bupivacaine depending on which study group you are in. For both groups, the anesthesiologist will use an ultrasound to look for the location where the nerves are located within your back; a needle will be inserted under direct ultrasound vision, and the local anesthetic will be injected in that area. The nerve block will take approximately 5 minutes to complete. Both study groups will stay asleep with an intravenous anesthetic medication called propofol. Medications such as pain medication and muscle relaxants will be given as needed to both groups. After the surgery, you will be taken to a surgery recovery area before you will go to your own hospital room. You will have pain medication and anti-nausea medication available, and the nurse will administer these medications if you need them. You will be periodically asked questions regarding your pain and nausea/vomiting during the rest of your hospital stay. A member of the study team will also call you after you go home from the hospital to ask you about your pain level and satisfaction with your anesthesia experience, functional status (ability to sit, stand, go to the bathroom, bath etc... with or without assistance), and your total use of opioid bsed medication. The phone conversation will take place on postoperative days 1,2, and 3 as well as during week 2, 6 and 12 and will last approximately 5 minutes.

- Because this project involves the use of medications or a medical device, 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.

USE OF YOUR DATA AND/OR SPECIMENS:

The private information collected as part of this research will never be used or shared for future research, even if the identifiable information is removed.

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:

- Periodically answering the post-operative questionnaires honestly either via telephone or in person (whatever is more convenient for you and depending on your location).

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you. You will not be reimbursed for your travel or time that may be required for study visits.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be improved functional outcomes after surgery such as being able to sit, stand, or walk sooner, decreased incidence of nausea or vomiting, decreased constipation, less pain medication required after surgery, decreased chance of the development of chronic pain, and you may be able to go home sooner because of a faster recovery.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

As stated above, the possible risks are bleeding, infection, damage to the surrounding tissue including but not limited to nerve and muscle damage. It is possible that this injection may cause an allergic reaction, a temporary drop in blood pressure, a temporary irregular heart rhythm or seizures. There is a risk that the injection may not be effective for pain control.
In addition to the risks mentioned above, the following represent additional risks incurred by participating in this research study.

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.
Instead of being in this research study, your choices may include: Proceeding with the surgery as planned and still having the choice to receive the erector spinae plane block injection if you desire it, but simply not be entered in the study.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

This does not prevent you from seeking payment for injury related to malpractice or negligence.
Contact the investigator for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff. We will simply stop contacting you and requesting you to answer our questionnaire.
If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your data removed from future use. If any data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place.

Withdrawal without your consent: The study doctor, the sponsor or the institution 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 study team have not been followed, the investigator believes it is in your best interest, or for any other reason.

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 Principal Investigator at 212-241-7473. If you experience an emergency during your participation in this research, please call 911 or go to the emergency room.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours 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 subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

The company sponsoring this research study (Pacira) manufactures the drug/device being tested and so has a financial interest that could be affected by the outcome of this research study.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be disclosed (shared) with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, date of birth, telephone number, date of surgery, date of discharge, and medical record number. The researchers will also get information from your medical record including your electronic anesthesia record and electronic medical record that documents your care during your recovery at Mount Sinai Hospital. They will also get information from your first postoperative visit with your surgeon. During the study, the researchers will gather information by completing the chart review and interviewing you during your hospital stay or doctor's appointment for any information that may not be included in your medical record, such as pain scores.

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

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 School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. 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 protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, 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 Principal Investigator.)

- The United States Department of Health and Human Services and the Office of Human Research Protection.

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 Principal Investigator 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 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 auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services 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. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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 Principal Investigator 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 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, *the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services 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.* We may publish the results of this research. However, we will keep your name and other identifying information confidential.

<u>For how long will Mount Sinai be able to use or disclose your protected health information?</u>

Your authorization for use of your protected health information for this specific study does not expire

<u>Will you be able to access your records?</u>

During your participation in this study, you will not be able to access your medical records. This will be 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 investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information 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?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

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 protected health information.

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, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

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) 306-5070. These agencies are responsible for protecting your rights.

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ADULT PARTICIPANT:

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

Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

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 subject, and that consent was freely given by the subject.

Signature of Witness	Printed Name of Witness	Date	Time