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## TITLE OF RESEARCH STUDY:

Quadratus Lumborum 2 Block vs Conventional Therapy Alone for Laparoscopic Sleeve Gastrectomy Surgery

## PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

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## WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

Basic information about this study will appear on the website http://www.ClinicalTrials.gov. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls "applicable clinical trials" 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.

## PURPOSE OF THIS RESEARCH STUDY:

You are here because you are scheduled to undergo a laparoscopic sleeve gastrectomy operation for weight reduction. The need for the surgery and your eligibility should have been determined and discussed by your surgeon.

The purpose of this study is to compare the pain relief that patients get from either conventional therapy with surgical wound infiltration with local anesthetics or the quadratus lumborum 2 (QL 2) block for patients having laparoscopic sleeve gastrectomy surgery. Conventional therapy means that a local anesthetic called bupivacaine 0.25% is injected directly into the tissue of the abdomen where the surgeon cuts. This conventional therapy has been used for many years, however the quality of pain control and the amount of time that patients remain pain-free is limited. For this reason, we want to compare pain relief with conventional therapy to the pain relief using a technique called the QL 2 block. The QL 2 block consists of injecting bupivacaine 0.25% into the outer layers of the quadratus lumborum muscle in the abdominal wall. This numbs the nerves that carry sensation from the abdomen and chest wall, thereby giving relief from the pain caused by the incisions the surgeon makes to perform the surgery. Both conventional therapy and the QL 2 block will be performed when you are still asleep. All patients will have general anesthesia (GA) which means that you will go to sleep with medications given in your intravenous (IV) line and have a breathing tube placed after you go to sleep. For this study, you will either receive conventional therapy or the QL 2 block.

The anesthesiologist in charge of this study will decide if you qualify for this trial. To qualify you must be scheduled to undergo a laparoscopic sleeve gastrectomy procedure and you must be medically able to receive both general anesthesia and the QL 2 block, as well as, being 18-65 years of age and have a body mass index (BMI) >35 kg/$m^2$. You will not be eligible for this trial if you have a history of allergy to local anesthetics, ketorolac, acetaminophen, or opioids, have a condition that would make it difficult for you to communicate with your doctor, or have a recent history of drug or alcohol abuse.

If you qualify, your doctor will explain the trial to you, including the risks and benefits so that you can decide if you would like to take part. If you decide to be

a part of the trial, your doctor will then open the trial randomization envelope to find out which treatment group you will be assigned to.

Funds for this research project are provided by Mount Sinai-St. Luke's and Mount Sinai-West Hospitals.

## LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last 48 hours.

The number of people expected to take part in this research study at Mount Sinai-St. Luke's and Mount Sinai West Hospitals is 110.

## DESCRIPTION OF WHAT'S INVOLVED:

On the day of your surgery, you will be assessed by the anesthesia and surgical teams. If you qualify for the study, you will receive either the QL 2 block or conventional therapy. Conventional therapy consists of the surgeon injecting bupivacaine 0.25% into the incision sites at the end of the procedure. The study treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose which study treatment you get. You will have a one in two chance of being given each study treatment. You will not know which study treatment you are getting. This information can be obtained in an emergency, however. You will not be told which study treatment you are getting, however your study doctor will know.

All procedures involved in this study will be performed at Mount Sinai-St. Luke's and Mount Sinai West Hospitals. Although the QL 2 block has been already extensively used for other surgeries, its ability to prevent pain in laparoscopic sleeve gastrectomies is being investigated here. We will be investigating two methods that are widely used for pain control and comparing them with each other. All drugs are being used in accordance with product labeling.

The main anesthetic for your surgery is called general anesthesia, which means you will be going to sleep after being given anesthetic mediactions through an intravenous line that will be placed by your anesthesiologist. After you are asleep, a breathing tube will be placed and your breathing will be controlled by a ventilator. Your blood pressure, oxygenation, heart rate, and breathing will be monitored throughout the performance of the anesthesia and surgery. If you are randomized to the conventional therapy group, then at the end of the procedure, but before you wake up, your surgeon will inject the incision sites with bupivacaine 0.25%. If you are randomized to the QL 2 group, then at the end of the procedure but before you wake up, your anesthesiologist will perform the QL 2 block. For the QL 2 block, an ultrasound probe will be placed on your abdomen and the correct muscle layers will be identified. The block needle will then be placed adjacent to the quadratus lumborum muscle under ultrasound visualization and the bupivacaine 0.25% will be injected into the lining of the muscle. A block needle consists of a hollow needle attached to tubing and a syringe is used to inject local anesthetic. The block needle is visible under the ultrasound and can therefore be placed in the correct location to do the QL 2 block. You will then wake up and the breathing tube will be removed in the operating room.

You will then be taken to the recovery room where you will be monitored by the nursing staff and assessed every hour by a researcher for the time that you remain in the recovery room. Things that will be assessed for data collection include your pain level, amount of pain medication consumed, and vital signs. You will be assessed several times by a member of the research team over the course of 48 hours after your surgery.

This study does not entail pregnancy risks, however a urine pregnancy test will be done for all female patients on the day of your surgery as part of the routine testing that is performed prior to surgery.

**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: answering questions about things like your pain, how much pain medicine you required, and the your general medical health. A member of the research team will be asking you these questions and your answers will be written on a data collection form that will then be entered into a computer database that will be encoded to keep your identity private. The data collection form itself will be stored in a locked cabinet in Mount Sinai-St. Luke's Hospital.

## 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 if you receive a QL 2 block may be a decrease in pain and the need for additional pain medications that are given by mouth or through your intravenous line. These pain medications have side effects such as nausea, vomiting, slowing of the breathing rate, and sedation.

## REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

There is a small risk, as with any injection, of bleeding or infection with insertion of the block needle.

Serious side effects such as a seizure or cardiac arrest related to bupivacaine 0.25% are rare, but may occur if too much is given or if it is accidentally injected into a blood vessel instead of into the surrounding tissues.

The numbing sensation caused by bupivacaine 0.25% may be persistent, with slow, incomplete, or no recovery. Sometimes a tingling sensation may appear in the area treated with local anesthetic.

Allergic reactions are rare, but may include rash, itching and redness of the skin, sneezing, nausea, vomiting, dizziness, fainting, sweating, fever, and low blood pressure.

If you experience any of the above side effects or other symptoms, you should notify the study doctor or study staff immediately.

By signing this Informed Consent Form, you do not give up any legal rights that you otherwise have as a subject in a research study. There always exists the potential for loss of private information; however, there are procedures in place to minimize this 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.

Other options to treat postoperative pain are available and include the placement of local anesthesia into the area where the surgeon is working and opioid medications into your intravenous line.

*The risks of these treatment options include absorption of the local anesthesia into your blood which can cause seizures or stop your heart.*

Please talk to your doctor about these choices and their side-effects before deciding if you will take part in this study.

## IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you are injured or made sick from taking part in this research study, medical care will be provided. The sponsor will reimburse your reasonable and necessary medical expenses for diagnosis and treatment of a research-related injury or illness.

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.

You may also 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 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 participating in the research study.

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. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

## CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number: 914-409-5023. If you experience an emergency during your participation in this research, contact Ali Shariat, M.D. at 914-409-5023. This research has been reviewed and approved by an Institutional Review Board. If you have questions about your rights as a research subject, please contact the Patient Representative Office: 212-523-3700.

If you experience an emergency during your participation in this research, call 9-1-1.

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.

## 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, address, telephone number, and medical record number.

The researchers will also get information from your medical record from Mount Sinai St. Luke's and Mount Sinai West Hospitals.

During the study the researchers will gather information by:

- taking a 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 interviews explained in the description section of this consent.

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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.

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.)

- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.

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.

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 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.

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## 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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**Signature Block for Capable Adult**

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 | Date |
| Printed name of subject | Time [required if used for FDA documentation purposes] |

**Person Explaining Study and Obtaining Consent**

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|---|---|
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | Time |

***Witness Section: For use when a witness is required to observe the consent process,, document below (for example, subject is illiterate or visually impaired, or this 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 to consent process* | *Date* |
| *Printed name of person witnessing consent process* | Time |