Effect of Unilateral Ultrasound-Guided Subcostal Transversus Abdominis Plane Block in Patients Undergoing Laparoscopic Sleeve Gastrectomy
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TITLE OF RESEARCH STUDY:

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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:

The purpose of this study is to determine the most effective combination of anesthesia techniques and strategies can best reduce pain after a laparoscopic sleeve gastrectomy surgery.

General anesthesia is routinely provided to patients undergoing laparoscopic sleeve gastrectomy surgery. General anesthesia is provided by inhaled anesthetic gas through a breathing device. Pain relief during the surgery and after the surgery is generally managed with intravenous narcotic pain medications, which are given through your IV.

Recently nerve blocks have been proposed as a way to potentially provide better pain control and recovery following surgery. This is used in addition to the general anesthesia that you would get for surgery. For the nerve block, the anesthesiologist will inject numbing medication (local anesthetic medication) around nerves in a specific portion of the body in order to numb the area for surgery. Sometimes the numbing medication can last for a duration after surgery as well, and hence, provide pain control following the surgery. Nerve blocks may help to decrease the amount of IV pain medications that you may need during or following surgery; this may lead to decreased nausea and vomiting and improved patient satisfaction. Patients may even require shorter hospital stay.

For laparoscopic sleeve gastrectomy surgeries (the surgery you are about to have), we are proposing to do a nerve block called the "subcostal transversus abdominis plane (TAP) block". We will use an ultrasound machine to identify the area and nerves of your abdomen that we want to block. We will then insert a needle under guidance from our ultrasound machine, and target the specific area. We will inject numbing medication in that area. This injection will take place after you have gone to sleep with general anesthesia. Nerve blocks have been shown to reduce pain for different types of abdominal surgeries. We believe that this specific nerve block, the subcostal TAP block, will help with pain control for your laparoscopic sleeve gastrectomy surgery. Our research study will test this hypothesis.

You may qualify to take part in this research study because you are an adult scheduled to undergo a laparoscopic sleeve gastrectomy surgery. You are not eligible to participate in this study if you have a history of liver or kidney problems.

Funds for conducting this research are provided by Mount Sinai.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last 1 to 5 days which includes your hospital stay and a follow up phone call. Your participation will end after a final follow-up phone call is performed 1-3 days after your discharge from the hospital.

The number of people expected to take part in this research study is 140.

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 subcostal TAP block with numbing medication (local anesthetic: bupivacaine). The second group will receive the subcostal TAP block with saline (salt water). 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

assigned. You will have a one in two chance of being in either group. The anesthesia you receive and the procedures that you may undergo as part of the study are all commonly performed for your surgery and other surgeries similar to it.

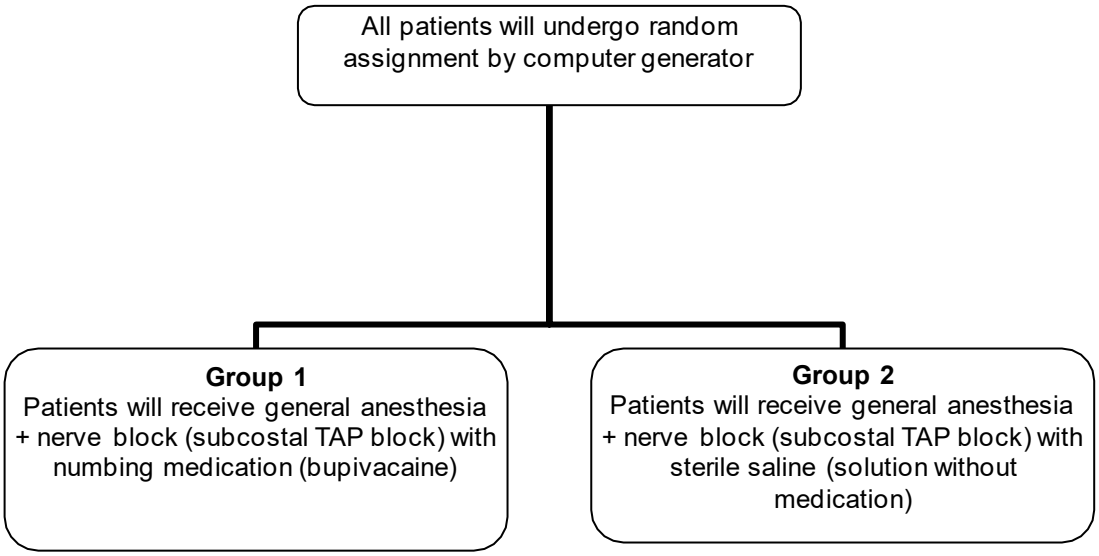
General anesthesia with or without a nerve block is commonly done for the surgery you are getting (laparoscopic sleeve gastrectomy). Both approaches are widely used at our hospital. Even if you were not part of the study, the anesthesia you would receive would be identical or very similar to one of these two approaches. While none of these approaches are investigational, we are conducting this study to see if any of them are superior to the others 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 saline instead of local anesthetic medication for your nerve block. This is to standardize the experiment and improve the integrity of the study. 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 laparoscopic sleeve gastrectomy surgery. You will get an 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 throat, which will be used to help you breathe during your surgery. Once the breathing tube is in place, the anesthesiologist will perform the subcostal TAP block with either local anesthetic or saline 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 abdomen; a needle will be inserted under direct ultrasound vision, and either the local anesthetic or saline will be injected in that area. The nerve block will take approximately 5 minutes to complete. Both study groups will stay asleep with inhaled anesthetic gas. Medications such as pain medication 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 and pain control. The phone conversation will take place about 1-3 days after you go home, and will last approximately 5 minutes.

Summary:



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 questions regarding your recovery after surgery, including your pain level, and presence of nausea or vomiting. These interviews will take place periodically during your hospital stay and through a phone interview 1-3 days after being discharged from the 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 may be reduced pain after surgery, reduced amounts of opioid pain medication needed for pain control, and fewer side effects such as nausea, vomiting, constipation, and sedation.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

A nerve block is often performed for the surgery you will have, even if a patient is not part of the study. Although rare, there are reported risks associated with nerve blocks such as the subcostal TAP block.

Possible risks with nerve blocks and this study include:

- Allergies to numbing medication
- Nerve injury

  This can occur if the needle goes into any nerves or if numbing medication is injected into a nerve. The numbing medication should be injected around the nerve. The nerves in the abdominal wall (where we are targeting) are small, so the chances of hitting the nerves are extremely small.
- Bowel damage

  It is rare but possible that the needle may enter the space where the bowel lies, which can potentially cause injury, infection, or bleeding. However, we use an ultrasound machine which can help us guide our needle to try to avoid this complication.
- Local anesthetic systemic toxicity

  An extremely rare side effect called "local anesthetic systemic toxicity" can occur when too much numbing medication builds up in the body, or is injected into unintended areas. Symptoms can range from mild to severe effects, such as lightheadedness, ringing noises in the ear, low blood pressure or heart rate, seizures, coma and death in extremely rare instances. Local anesthetic systemic toxicity is extremely rare, especially for nerve blocks in the abdomen. Use of an ultrasound machine also helps to minimize injection into unintended areas of the body.
- Loss of private information

  There is a risk of loss of private information; this risk always exists, but there are procedures in place to minimize this risk.
- Possibility of not getting improved pain relief

  If you are randomized to the group receiving the nerve block with saline instead of medication, you may not have improved pain relief. You will not know which group you are in, but you will have access to additional pain medications postoperatively if you require them.

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.

If you choose to not be involved in this research study, you may still be offered a nerve block as part of your anesthesia management.

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. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. 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: 212-241-7473.

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, 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 from EPIC and Compurecords, which are where the medical records are stored.

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 tests, procedures, questionnaires and interviews explained in the description section of this consent.
- Reviewing medical chart records

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 Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

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 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.

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

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 have access to your medical record and any study information that is part of that record. 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.

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

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