Transabdominal Plane (TAP) Blocks for Inguinal Hernia Repairs
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STUDY INFORMATION:

Study Title: Transabdominal Plane (TAP) Blocks in Laparoscopic Inguinal Hernia Repair

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

Lead Researcher (Principal Investigator): Celia M Divino, MD

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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.

An inguinal hernia is a weakness in the layers of your abdominal wall through which abdominal contents may bulge and get stuck. The bulge may be transient, but there is a risk that the abdominal contents get stuck. Due to this risk, patients may elect to have the weakness repaired surgically.
There are multiple methods to help manage pain after surgery. Patients may be given oral or intravenous medication for their pain. Another form of pain management that patients can elect to have is a local anesthetic block performed in the abdomen called a transabdominal plane (TAP) block. This will be done prior to surgery (while you are under general anesthesia) and may help decrease pain related to the incisions made during surgery and thus decrease the use of additional pain medication after the operation

The purpose of this study is to assess whether TAP blocks reduce opioid requirements and pain scores after inguinal hernia repair. In this study, you will be randomly assigned to receive either (1) standard local anesthesia at the incision sites + the TAP block or (2) standard local anesthesia at the incision sites + a placebo saline injection during your inguinal hernia repair. Two different formulations of local anesthetics will be used for the TAP block. This study will be blinded, meaning you will not know if you are receiving the TAP block with medication or with saline. Your chances of receiving the TAP block are 50% (like the flip of a coin). Both group one and two are currently standard of care; in other words, regardless of which group you are randomized to, you will not be undergoing any novel procedures or receiving new medications that are not currently used in standard practice. Additionally, the duration of the operation will be equivalent for both groups.

If you choose to take part, you will be asked to sign the research consent form. In addition, after the hernia repair surgery you will be discharged from the hospital with a worksheet on which you are to record your analgesic (pain relieving) use and pain scores (called “metrics”) on postoperative days one, two, three and four. You are asked to bring the completed log to your two-week follow up visit with your surgeon. You will also receive a phone call from a member of the surgical team on postoperative day two or three (approximately 5 minutes in duration) to remind you to record these metrics.

If you choose to take part, the main risks to you are The main risks to you if you choose to participate include postoperative sensation of pain and discomfort, prolonged stay in the hospital, side effects from anesthetic medications, and discomfort from injection site of TAP block. There is also the risk of local anesthetic systemic toxicity (LAST), which occurs when the anesthetic agent is injected into a systemic blood vessel

You may benefit from taking part in this research. Some potential benefits may include decreased pain after surgery, a shorter hospital stay and a quicker return to normal function.

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 are undergoing laparoscopic (surgery done using a camera placed through a small incision cut) inguinal hernia repair.

Your participation in this research study is expected to last the duration of your hospital stay and to the first follow-up outpatient appointment.

There are 100 people expected to take part in this research study Mount Sinai Hospital.

Funds for conducting this research study are 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 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:

In this study, you will be randomly assigned to receive either (1) the TAP block or (2) a placebo saline injection during your inguinal hernia repair. Two different formulations of local anesthetics will be used

for the TAP block. This study will be blinded, meaning you will not know if you are receiving the TAP block with medication or with saline. Your chances of receiving the TAP block are 50%. Both group one and two are currently standard of care; in other words, regardless of which group you are randomized to, you will not be undergoing any novel procedures or receiving new medications that are not currently used in standard practice. Additionally, the duration of the operation will be equivalent for both groups.

If you choose to participate, you will be asked to sign the research consent form. In addition, after the hernia repair surgery you will be discharged from the hospital with a worksheet on which you are to record your analgesic use and pain scores (called “metrics”) on postoperative days one, two, three and four. You are asked to bring the completed log to your two-week follow up visit with your surgeon. This visit is standard and will be conducted in the same manner as it would be if you were not enrolled in the study. The only difference is that you will return your worksheet. You will also be asked to answer questions regarding the severity of your pain on that day, again which is standard of practice (“What is your current pain level, on a scale from 1-10, at rest today?” and “What is your current pain level, on a scale from 1-10, when you cough or move?” and “What are you taking to control your pain, and how much are you taking?”). You will receive a phone call from a member of the surgical team (approximately 5 minutes in duration) on postoperative day two or three to remind you to record these metrics.

Because this research study involves the use of a TAP block, a note must be included in your electronic medical record that you are taking part in the research. This way, anyone involved in your medical care will know that you are a study participant, and they can work to avoid any problems or negative outcomes that could arise if they do not know.

Randomization

No one, not you, or anyone from your medical team or from the research team will be able to choose what group you are assigned to or what study drug you get. It will be by chance, like flipping a coin. You will have an equal chance of being given a TAP block or placebo. Neither you nor the Lead Researcher or your own doctor will know which study drug you are getting. If there is an emergency, they can get this information.

USE OF YOUR DATA AND/OR SAMPLES:

The researchers would like your permission to keep your personal information (such as, name, address, date of birth) or study data to use or share in future studies. Before anything is shared, all of your identifying personal information will be removed and it will be replaced with a code. Researchers are not planning on giving you the details of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project. You can still be part of the study if you do not allow us to use or share them. Please

select Yes or No to each of the questions below. To decline all future uses/sharing please select 'No' each time.

(1) Will you allow the researchers to store your data and/or samples to use in future research studies?

Please initial your choice: Yes_____ No_____

If you select No, please stop here and move to the next section, 'Your Responsibilities If You Take Part in This Research' section below."

If yes, please continue to the next question and tell us how your personal information, study data and/or samples may be used in future research studies.

(2) Do you give the researchers permission to keep the data and/or samples, so they could use them in future studies that are directly related to the purpose of the current study?

Please initial your choice: Yes_____ No _____

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:

Signing of the research consent form. In addition, you will be discharged with a worksheet on which you are to record your analgesic use and pain scores on postoperative days one, two, three and four. You are expected to bring the completed log to your two-week follow up visit with your surgeon. You will receive a phone call from a member of the surgical team between three and four days after you have been discharged from the hospital to remind you to record these metrics.

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.

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:

It is important to know that you may not benefit from taking part in this research and it is possible that others may not benefit either. However, possible benefits may include decreased pain after surgery, a shorter hospital stay and a quicker return to normal function.

POSSIBLE RISKS AND DISCOMFORTS:

Possible risks of study participation include potential risk of bowel injury, postoperative sensation of pain and discomfort, prolonged stay in the hospital, side effects from anesthetic medications, and discomfort from injection site of TAP block. There is also the risk of local anesthetic systemic toxicity (LAST), which occurs when the anesthetic agent is injected into a systemic blood vessel. All injections of anesthetic carry a <1% risk of local anesthetic systemic toxicity (LAST) which can cause seizures or even cardiac arrest. Common side effects include temporary loss of feeling in the abdominal area, decreased muscle strength, dizziness, nausea/vomiting, drowsiness, ringing in ears, tremor, vision changes and headache. The risk of psychological harm is minimal or low. (or something to that effect). You may feel uncomfortable discussing your medical history with the members of the research team.

There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk.

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.

- *Proceeding with the surgery without a TAP block*
- *Proceeding with the surgery with a TAP block*
- *Proceeding with watchful waiting (to select patients with asymptomatic or mildly symptomatic groin hernias)*

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.

If you are injured or made sick from taking part in this research study, you will get medical care. Generally, it will be billed to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, copayments, and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

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 stop being in the research study, the research team may not remove information they have already placed in the study database, and may continue to use that data as part of this study. The research team may ask you whether they can continue to collect information from your medical record.

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 withdrawn or labeled so that they will not to be used in additional projects or shared. If your data have already been shared with researchers, those researchers will be asked to stop using them. However, if any data have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data that have already been used will not be affected by your decision. If your data 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 212-241-5499.

If there is an emergency, please contact your primary care physician or call 911 or go to the emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed.

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.

The principal investigators have no financial interests to disclose.

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 study, the research team at the hospital(s) involved in the research will collect your address, telephone/fax numbers, dates directly related to the individual (birth, admission, discharge, date of death, etc.), e-mail addresses, medical records number.

The researchers will also obtain information from your medical record at the Mount Sinai Hospital or from your private doctor.

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.

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 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.
- I*f 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).

- The United States Food and Drug Administration.

In all disclosures outside of Mount Sinai, you will not be identified by name, 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 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 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.

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.

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:
When a witness is required to observe the consent process, it should be documented below (for example, when participant 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 participant, and that consent was freely given by the participant.

Signature of Witness	Printed Name of Witness	Date	Time