Informed Consent for Participation in a Research Study

Title of Research Study: Postoperative Pain Control with Systemic Lidocaine vs Regional Anesthesia in Renal Transplant Patients
Investigator: Dr. Marian Sherman, Anesthesiology and Critical Care Medicine

Key Information:

You are being asked to take part in a research study about ways to treat surgical pain after a kidney transplant. This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process, and use the contact information on this form to ask questions later.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?
This study aims to determine whether a nerve blocks or a lidocaine infusion is better at controlling pain after kidney transplantation. While nerve blocks and lidocaine infusions are both effective ways to control pain and are already in use at GW hospital, there has been no study comparing which is better at controlling pain after kidney transplantation. By doing this study, we hope to learn which treatment method yields better pain control. Your participation in this research will last about 48 hours after your surgery.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
While this study might not have direct benefit to you, the information we learn from this study will help physicians better treat post-surgical pain and identify ways of treating post-operative pain without using opioid pain medication. For a complete description of benefits please refer to the Detailed Consent.

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?
As with any medication, there are risks to receiving lidocaine or ropivacaine (the medication used in nerve blocks). While these drugs are relatively safe and already used regularly here at GW hospital, we will still take all necessary precautions when administering these medications. For a complete description of risks please refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THIS STUDY?
You do not have to take part in this research. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

WHAT IF YOU HAVE QUESTIONS OR CONCERNS?
The person in charge of this study is Dr. Marian Sherman. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is:

Dr. Marian Sherman
Anesthesiology and Critical Care Medicine, GW Medical Faculty Associates
2300 M St. NW, 7th floor
Washington DC, 20037
msherman@mfa.gwu.edu
202-715-4750

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

Detailed Consent Form:

Why am I being invited to take part in a research study?

We invite you to take part in a research study because your medical records show you will be receiving a kidney transplant.

What should I know about a research study?

- Someone will explain this research study to you. You may ask all the questions you want before you decide whether to participate.
- Participation is voluntary; whether or not you take part is up to you.
- You can agree to take part and later change your mind.
- Your decision not to take part or to stop your participation will not be held against you.
- Your decision will not affect the medical care you receive from GW. If you decide not to take part, you can still receive medical care from GW.
- You may discuss with your family members or doctor before deciding to take part in this research study.

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. 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.

Who can I talk to if I have questions?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Principal Investigator at:

Dr. Marian Sherman
Anesthesiology and Critical Care Medicine, GW Medical Faculty Associates
2300 M St. NW, 7th floor
Washington DC, 20037
msherman@mfa.gwu.edu
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Why is this research being done?

This study aims to compare the effectiveness of different ways of treating pain after a kidney transplant surgery. The goal is to find ways to treat surgical pain while using as little opioid medication as possible.

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How long will I be in the study?

We expect that you will be in this research study for 48 hours following your surgery.

How many people will take part in this research study?

We expect about 80 people will take part in the entire study.

What happens if I agree to be in this research?

Your involvement in this study will begin once you reach the post-anesthesia care unit (PACU) following surgery and last for 48 hours.

All patients, regardless of participation in this study, will receive a patient-controlled analgesia (PCA) pump as part of standard post-surgical care. The PCA pump is a device filled with pain medication, typically Dilaudid, and connected to the patient through an IV line. Dilaudid is an opioid medication regularly used to treat post-surgical pain. A computerized pump attached to the IV lets you release pain medicine by pressing a handheld button. The device is programed limit the amount of medication delivered every hour to prevent overdose. If you participate in this study, you will receive a PCA pump in addition to the different pain control methods being examined in this study.

Your study group assignment will be chosen by chance, like flipping a coin. You will have an equal chance of being assigned to any of the following two groups:

1. Lidocaine group: this group will receive lidocaine infusion through an IV in addition to a PCA pump. Lidocaine (a non-opioid analgesic) is a medication typically injected under the skin to cause local numbness. When infused through an IV, lidocaine will decrease the overall level of pain throughout the body. For this study, lidocaine will be administered through an IV bag and will be infused continuously through an IV line while you are in the hospital.
2. Nerve block group: this group will receive a nerve block catheter in addition to a PCA pump. This is a catheter that is inserted through the skin near the surgical site and is placed while in the operating room as part of the kidney transplant surgery. This catheter is left in place for several days. This catheter is connected to a medication pump that will infuse a numbing medication, Ropivacaine, into the tissue and muscle (transverse abdominis muscle specifically) around the surgical site.

Besides these treatments, you will receive all the standard medications and treatments for postoperative pain that kidney transplant patients normally receive. During your hospital stay, your nurse will regularly ask you to rate your pain level. This is part of your routine care while admitted and would be done regardless if you participate in this research project or not. The research team will collect information about your recovery for 48 hours following your surgery. This information will be collected from your medical chart.

If you agree to participate in this study, a copy of this consent form will be placed in your medical records.

What are my responsibilities if I take part in this research?

While in the hospital, your nurse will regularly ask you to rate your pain level. This is part of your routine care while admitted and would be done regardless if you participate in this research project or not.

What other choices do I have besides taking part in the research?

The alternative to participating in this research study is to not participate. The standard of care you will receive will not be affected by your decision to participate in this study.

If you decide to not participate in or to withdraw from this study, it is still possible that your surgeon may prescribe a PCA, lidocaine infusion, or nerve block. At GW Hospital, these treatment methods are frequently used to control pain after large surgeries and are prescribed based on the choice of your surgeon.

What happens if I agree to be in research, but later change my mind?

You may refuse to participate or you may discontinue your participation without penalty or loss of benefits to which you would otherwise be entitled. If you decide to leave the research, you will receive the standard of care for post-renal transplant surgery.

If you decide to leave the research, contact the investigator so that the research team can remove any data that was collected on you from the research files.

Is there any way being in this study could be bad for me?

Risks of Patient Controlled Analgesia (PCA): opioid overdose, dangerously slow breathing rate (respiratory suppression), tiredness, itching, constipation, risk of opioid addiction, allergic reaction to opioids.

The PCA is the current standard of care. You will receive a PCA regardless of the study group you are placed in. Standard precautions against risks include heart and oxygen saturation monitors (for overdose, respiratory suppression, and lethargy), a lock out button on the pump that limits the amount of medication you can receive (prevent overdose), stool softeners (for constipation), and reducing dose of opioid medications as quickly as possible (avoid addiction).

Risks of Lidocaine infusion: allergic reaction to lidocaine, lidocaine toxicity (symptoms include lightheadedness, dizziness, visual changes, confusion, ringing in the ears, and numbness around the mouth and in the fingers)

You cannot participate in this study if you have a history of allergies to lidocaine or similar local anesthetic. If you receive lidocaine as part of this study, you will be monitored for signs of lidocaine allergy or toxicity. If adverse reactions to lidocaine are noted, the lidocaine will be stopped and you will be treated per standard of care. If this were to happen, you will be removed from the study.

Risks of nerve block: local infection, large area of bruising, poor placement leading to poor pain control

The nerve block catheter will be placed in the operating room to best ensure correct placement, avoid bleeding and hematoma (pooling of blood under the skin) formation, and to

minimize risk of infection. The insertion site of the nerve block catheter will be examined per standard of care by the surgical team. If infection or a hematoma is noted, the catheter will be removed per standard of care and the infection or hematoma will be treated per standard of care.

There is always a minimal risk of loss of confidentiality in the process of data collection and analysis. Appropriate precautions will be taken to safeguard all patient information.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. All services provided in this study are standard of care or are routinely used adjuncts to standard of care and may be provided to you whether or not you participate in this study. As with all care that you receive in the hospital, you should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens if I believe I am injured because I took part in this study?

The researchers have taken steps to minimize the known or expected risks. In spite of all precautions, you still may experience medical complications or side effects from participating in this study. You should promptly notify the study doctor in the event of any illness or injury as a result of being in the study.

If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment from GWU Hospital and/or the GWU MFA or through your physician or treatment center of choice. Care for such injuries will be billed in the ordinary manner to you or your insurance company.

You will not receive any financial payments from GWU, GWU Hospital and/or the GWU MFA for any injuries or illnesses. You do not waive any liability rights for personal injury by signing this form.

Will being in this study help me in any way?

We cannot promise any direct benefits to you or others from your taking part in this research. Previous studies have shown that lidocaine infusions and nerve blocks may decrease the need for opioid medications, but this is not guaranteed. It is also not guaranteed that your overall pain levels will be less by taking part in this research. Data from this study will be used to design more effective treatments for post-surgical pain for future patients.

Can I be removed from the research without my permission?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include having an allergic reaction to or medical complication from one of the medications, or having a complication from your surgery that requires you to be on a treatment plan different from what can be given in this study.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

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What happens to my information collected for the research?

Only data necessary to this study will be collected. Any data that is collected will be securely stored. To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. The IRB and other representatives of this organization may inspect and copy your information.

How will my privacy and health information be protected?

The Health Insurance Portability and Accountability Act (HIPAA) requires that researchers and health care providers protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions, or the provision of health care. If you agree to participate in this research, protected health information will be used and shared with others for purposes of the study. Below is more detailed information about how your health information will be shared and protected. By signing this form, you are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form.

The use and release of protected health information is for the purpose of collecting data for this study.

Protected Health Information to be shared: age, gender, date of surgery, date of hospitalization, date of discharge from the hospital, medical history, medications given in the hospital, and prescription medicines taken at home.

The researcher and the other members of the research team may obtain your individual health information from: hospital medical records and the surgery team

By signing this form, you allow the use, sharing, copying, and release of your protected health information in connection with this study by:

- The members of the research team;
- Institutional officials who are responsible for compliance;

Once your health information has been disclosed to others outside of the hospitals and medical practices, the information may no longer be covered by the federal regulation that protects privacy of health information. No part of this study requires that your information be disclosed to others outside of this hospital.

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct this study.

This Authorization does not have an expiration date. However, you may cancel this authorization at any time. Even if you cancel this authorization, the researchers may still use the protected health information they already have about you; however, no new health information or new biological specimens will be collected from you after you cancel your permission.

To cancel your permission, you will need to send a letter to Dr. Sherman stating that you are canceling your authorization. This letter must be signed and dated and sent to this address:

Dr. Marian Sherman
Anesthesiology and Critical Care Medicine, GW Medical Faculty Associates
2300 M St. NW, 7th Floor
Washington DC, 20037
msherman@mfa.gwu.edu
202-715-4750

Are there any costs for participating in this research?

There are no additional costs to you for participating in this research. The costs associated with your surgery, subsequent treatments, and hospital stay will be billed to you or your insurance as it normally would regardless of your participation in this study.

Will I be paid for my participation in this research?

No, there will be no payment for participation in this research.

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Signature Block for Adult

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research.

_____

Printed name of subject

_____ _____

Signature of subject Date

_____ _____

Signature of person obtaining consent Date