APPROVED BY
THE INSTITUTIONAL REVIEW BOARD
September 28, 2023
APPROVAL DATE
ALLEGHENY HEALTH NETWORK
Study ID# 2019-125-WPH

INFORMED CONSENT FORM AND AUTHORIZATION TO DISCLOSE PROTECTED HEALTH INFORMATION FOR A RESEARCH STUDY

1 - (2019-125): The Impact of Retropubic Lidocaine vs Saline on Postoperative Urinary Retention Following Midurethral Sling: A Randomized Placebo Controlled Trial

2 – Principal Investigator:

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3 - Sponsor: None

4 - Concise Summary:

Concise Summary

The purpose of this research study is to compare the impact of retropubic (behind the pubic bone) lidocaine versus placebo on postoperative urinary retention and pain in patients undergoing retropubic midurethral sling placement. This project is considered “Research” and participation is voluntary.

If you agree to participate in this research study, you will complete a brief pain questionnaire prior to your surgical procedure in the pre-operative area on the day of your surgery. Study staff will record research data from your medical record on study forms that do not contain your name or other identifying information. You will be randomly assigned to receive a medication (lidocaine) or placebo (salt water) during surgery. You will have a 50:50 chance of receiving this drug. Neither you, your surgeon, your anesthesiologist nor any member of the research team can determine whether you will receive the drug or the placebo. You will undergo a voiding trial 1-2 hours postoperative in order to see if you are able to go to the bathroom by yourself. You will be asked to complete questionnaires about your pain, daily activities, and satisfaction with your surgery; and to fill out a pain diary. Your participation will last approximately 6 weeks following your surgery.

Risks associated with study participation include pain if taking the placebo, allergic reaction to lidocaine, and post-operative urinary retention. You will be monitored closely for these events. There is also a possible loss of confidentiality. We take great care to minimize this chance by not recording your personal information (like your name) on forms and keeping our records in a locked office. Benefits of participating in this study cannot be guaranteed, but include a reduction in post-operative urinary retention, improved patient satisfaction, and quicker return to activities following surgery.

The alternative to participating in this study is to undergo the current standard practice of receiving retropubic lidocaine during sling placement.

If you are interested in learning more about this study, please continue reading below.

5 - What you should know about a research study

- Someone will explain this research study to you.
- Being in a research study is voluntary.
- Whether or not you take part is your decision.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.
- "You" refers to you as a participant in this study.

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study doctor or study staff if you are taking part in another research study.

6 - Who can I talk to if I have questions?

If you have questions, concerns, or complaints, or think the research has hurt you, you should contact the principal investigator Dr. Lindsay Turner at Lindsay.Turner@ahn.org.

This research has been reviewed and approved by AHN RI Institutional Review Board. You may talk to them by calling this toll-free number, 1-844-577-4621, for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

7 - Why are you doing this research?

We invite you to take part in a research study because you are scheduled to undergo retropubic midurethral sling placement at our institution for treatment of your urinary incontinence. Although the advantages of midurethral sling surgery include its high success rates and minimally invasive approach, approximately 10-50% of women experience acute postoperative urinary retention and are subsequently sent home with an indwelling foley catheter or clean intermittent self-catheterization. Several mechanisms could explain the inability to void postoperatively, including nerve conduction impairment from anesthesia. We aim to investigate the effect of whether or not using local anesthetic has any downstream effects on postoperative urinary retention and postoperative pain.

8 - How long will the research last?

We expect that you will be in this research study from the day of your surgery through 6 weeks following your surgery.

9 - How many people will be studied?

We expect approximately 160 patients will enroll at West Penn Hospital, Bethel Park Health & Wellness Pavilion, Wexford Health & Wellness Pavilion, and Jefferson Hospital.

10 - What happens if I say yes, I want to be in this research?

If you agree to participate in this research study, you will complete a brief pain questionnaire prior to your surgical procedure in the pre-operative area on the day of your surgery. You will write the answers to the questions on paper.

Study staff will record research data from your medical record. All of this information was collected as part of your clinical visit with your doctor. Study staff will simply record some of this information on study forms (that do not contain your name or other identifying information). Things that they will record include your age, race, ethnicity, body mass index, current medications, smoking status, bowel habits, questions related to urinary and fecal incontinence, medical and surgical history.

You will be randomly assigned to receive a medication (lidocaine) or placebo (salt water) during surgery. You will have a 50:50 chance of receiving either the medication or placebo. Neither you, your surgeon, your anesthesiologist, nor any member of the research team will determine whether you will receive the medication of placebo. You will then undergo a voiding trial 1-2 hours postoperatively in order to see if you are able to go the bathroom by yourself.

Before and after surgery you will be asked to fill out a brief pain questionnaire. In addition, 24 hours after your procedure you will be asked to fill out questionnaires about the quality of your pain control, any side effects you may have experienced as a result of any of the pain medications you received, and patient satisfaction and mood.

You will also be asked to keep a pain diary at home for the first week of your recovery. In this diary, you will be asked to record when you take pain medications. You will mail this diary back to the study office in a pre-addressed and stamped envelope.

You will be asked to complete a brief questionnaire 1 week after surgery about your ability to perform your daily activities and your satisfaction with your pain control. You will have the option of completing this questionnaire on paper and mail it to the study office in a pre-addressed and stamped envelope or online over a secure website. At your 6-week follow-up clinic visit, you will be asked about your satisfaction with the procedure.

All office visits, surgery and follow up appointments will be completed at West Penn Hospital, Bethel Park Health & Wellness Pavilion, or Wexford Health & Wellness Pavilion, whichever location is most convenient for you. We expect that you will be in this research study from the day of your surgery through 6 weeks following your surgery.

11 - What happens if I say no, I do not want to be in this research?

Participation in this research is voluntary. You may decide not to take part in the research, and it will not be held against you. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide not to take part, it will not affect your current or future relationship with our department.

Instead of being in this research study, you will simply undergo our current practice standard of receiving retropubic lidocaine during sling placement.

12 - What happens if I say yes, but I change my mind later?

If you agree to take part in the research now you may stop at any time, and it will not be held against you. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to leave the research, contact the investigator at the contact information listed on page 1 of this consent so that you may be removed from participation safely. Study data collected up to the point of study withdrawal will be retained to maintain the integrity of the study. The study team may ask your permission to collect further data from routine medical care after your study participation ends.

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

General risks associated with participating in this study include possible increased pain due to lack of lidocaine if you receive the placebo, allergic reaction to lidocaine if you receive this treatment, and post-operative urinary retention. You will be monitored closely throughout the study for these events. There is, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential. Your medical chart and outcomes will remain confidential. The records of this study will be kept private. Research records will be kept in a locked file; only the researchers will have access to the records.

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, and you may take a break at any time during the study.

14 - Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a reduction in postoperative urinary retention and improved patient satisfaction, mood, and quicker return to activities following retropubic midurethral sling placement.

15 - Will my information be kept confidential?

Your identity and medical records and data related to this study will be kept confidential, except as required by law and except for inspections by the U.S. Department of Health and Human Services (HHS), the U.S. Food and Drug Administration, Allegheny Health Network, the Allegheny Health Network Research Institute, the AHN RI Institutional Review Board (the committee formed to protect the rights and welfare of human subjects involved in research activities being conducted under its authority)) and the AHN Compliance Office. Results of the research may be published for scientific purposes or presented to scientific groups; however, your identity will not be revealed.

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.'

Federal law provides additional protections of your personal health information. These are described below in the **HIPAA Authorization Statement below.**

16 - Can I be removed from the research without my approval?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff, if you do not complete questionnaires or return for your follow up appointment as instructed, and/or if the person in charge decides that the research study is no longer in your best interest. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

17 - Are there costs of participating in this study?

This kind of research study is not expected to result in any costs to you or your insurance company. If you require medical care for your urinary incontinence or other health problems, as part of your routine care (care you receive even if you do not participate in this research study), either you or your insurance carrier

will be billed for these charges.

There are certain tests and examinations that are part of the normal standard of care for patients diagnosed with *urinary incontinence*. The cost for the standard of care items will be billed to you or your insurance company as usual. If you require additional medical care for urinary incontinence or other health problems, as part of your standard medical care, either you or your insurance carrier will be billed for these additional charges.

Please also talk with the study doctor about any expected added costs or health insurance problems.

18 - Will I be paid to participate in this study?

You will not be paid for your participation in this research study.

19 - What if I am injured while taking part in this study?

If you are injured or made sick while taking part in this research study, emergency medical treatment will be provided at the usual charge. No funds have been set aside by Allegheny Health Network or Allegheny Health Network Research Institute to pay you in case you are injured. You do not waive any of your legal rights to compensation, if any, by signing this form.

Please contact the study team immediately if you believe you have been injured during this study.

***20* - Authorization to Use and Disclose Individually Identifiable Health Information for a Research Study (HIPAA Authorization Statement)**

Before you can take part in this research study, the Allegheny Health Network is required to obtain your authorization to use and/or disclose (release) your health information. This section describes to you how, and to whom, your health information will be used and/or disclosed (shared) while you are participating in this research study. It is important that you read this carefully. Allegheny Health Network and its' researchers are required by law to protect your health information.

The following is a list of health information that will be used and/or disclosed:

1. Demographic Information (e.g., age, race/ethnicity)
2. Medical record information (e.g., medical, and surgical history, pre- and post-operative information)
3. Surveys/questionnaires

The following is a list of entities that may use and/or disclose your health information as part of this study:

Internal Oversight

Those who oversee the study will have access to your health information, including the following:

- Allegheny Health Network
- Allegheny Health Network Research Institute
- AHN Compliance Office
- The AHN IRB
- Study Doctor and Study Staff

Allegheny Health Network

Governmental Oversight

Your health information may also be shared with government agencies that have oversight of the study or to whom access is required under the law:

- U.S. Department of Health and Human Services (HHS)
- U.S. Food and Drug Administration (FDA)

Others Outside Allegheny Health Network

The following persons and/or organizations outside of Allegheny Health Network may also use, disclose, and receive your health information in connection with this study:

- None

In order to participate in this study, you must agree to share your health information with the persons and organizations listed above. If these persons or organizations that you authorize to receive and/or use protected health information, are not health plans, covered health care providers or health care clearinghouses subject to federal health information privacy laws, they may further disclose the protected health information and it may no longer be protected by the federal health information privacy laws.

Expiration of Authorization

This authorization will not expire unless you revoke it in writing. You may revoke or end this authorization by writing to the Principal Investigator:
Dr. Lindsay Turner
4815 Liberty Avenue
Mellon Pavilion, Suite GR30
Pittsburgh, PA 15224

If you revoke your authorization, you will also be removed from the study. Revoking your authorization only affects the use and sharing of your health information after the written request is received. Any health information obtained prior to receiving the written request may be used to maintain the integrity of the study.

Authorization

By signing this document (authorization), you authorize that your health information can be used and/or disclosed as described.

Your access to your protected health information created or obtained by Allegheny Health Network in the course of the research (that includes treatment) may be temporarily suspended for as long as the research is in progress. By signing this document, you are agreeing to the denial of access to your protected health information, created for the research, while you are participating in this research study. Your access to your protected health information will be reinstated upon completion of the research. If you choose to not sign this document, you will not be permitted to participate in this research study.

Allegheny Health Network

Consent – (Signature Block for Capable Adult)

Your signature below indicates your permission to take part in this research and to the use and disclosure of your protected health information. You will be given a signed copy of this consent form.

Signature of Subject	Date
Printed Name of Subject	Time – include AM/PM
Signature of Witness to Signature	Date
Printed name of Witness to Signature	Time – include AM/PM
Signature of Physician Investigator / Qualified Practitioner	Date
Printed Name of Physician Investigator / Qualified Practitioner	Time – include AM/PM