Informed Consent Form

A comparison of pain perception using topical EMLA cream versus lidocaine injection for vulvar biopsy: a randomized controlled trial

NCT03654417

ICF approved November 11, 2018

DUKE UNIVERSITY HEALTH SYSTEM

PI: Laura Havrilesky, MD

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CONCISE SUMMARY

There are two approved numbing medicines for vulvar biopsies. The purpose of this study is to see if one of them is better tolerated by and/or more acceptable to patients. To do this we will compare pain control during vulvar biopsy following either application of EMLA (a Eutectic Mixture of Local Anesthetics; a numbing cream used on the skin) or injection of lidocaine. Participating in the study requires additional time in clinic to answer research related questions. You will be asked to answer some questions about yourself, to rate your pain at three different times during the procedure, and to tell us if you felt the procedure was acceptable to you. The numbing medicine you receive will be randomly assigned to you, so you have a 50/50 chance of receiving either medication.

You may not benefit from participating in this study. If you are in the EMLA cream group, you will not receive a needle injection for anesthesia. There is a risk of skin reaction at the site of application of the anesthesia. This might result in being unable to perform the vulvar biopsy today and would necessitate a return clinic visit after the irritated area has resolved.

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

INTRODUCTION

You are being asked to take part in this research study because you are planning to have a vulvar biopsy at the Duke Gynecology Oncology Clinic or the Duke Womens Cancer Care Raleigh clinic. 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.

Dr. Laura Havrilesky and her colleagues are conducting this study and it is being funded by the Duke University Department of Obstetrics and Gynecology.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, your regular healthcare provider will continue to be your doctor for the study.

WHY IS THIS STUDY BEING DONE?

We are performing this study to evaluate pain control during vulvar biopsy using two different numbing medicines and to analyze patient's perspectives about the acceptability and tolerability of the procedure.

Specifically, we are comparing patient perceived pain after the application of topical EMLA numbing cream versus patient perceived pain after an injection of lidocaine. We will do this by collecting pain

scores from participants at three different time points during their vulvar biopsy procedure. We will also ask participants and the person performing the biopsy questions about the tolerability and acceptability of the procedure.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 120 people will be consented to take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. A signed copy will be sent to the email address you provide or printed and provided to you for your records.

You will be randomly assigned (like the flip of a coin) to receive either EMLA cream or injected lidocaine prior to your vulvar biopsy, both of which are FDA-approved. You have a 50% chance of receiving either the EMLA cream or the lidocaine injection. All participants will receive some kind of numbing medicine prior to their procedure.

In this study, you will receive all of the normal physical examinations and teaching about the biopsy procedure that are standard of care for this procedure. The biopsy site(s) will be identified and the anesthetic will be applied.

If you are selected to receive EMLA cream, you will wait 10 minutes with the cream in place before the biopsy is done.

If you were selected to injected lidocaine, you will receive injected lidocaine at the site(s) of biopsy and at least 1 minute will pass before the biopsy is performed.

You will also be asked questions at three time points:

1. Before your biopsy- You will be asked some basic questions about yourself. You will also be asked to rate your baseline anxiety and pain.
2. After the administration of numbing medicine- You will be asked to rate your pain level.
3. After your biopsy- You will be asked to rate your post-procedure pain level and to answer questions about your experience and whether you felt the procedure was acceptable and tolerable.

You may decide at any time during your clinic visit to withdraw from the study. Withdrawing from the study will not result in any changes in your care or your relationship with your provider or the care that you receive.

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If you decide not to sign the consent form, you will continue to receive the indicated care, but it will not be as part of this study.

HOW LONG WILL I BE IN THIS STUDY?
Your participation in this study will be for the duration of your clinic visit today. Once you have completed the post-procedure survey, your participation will be complete.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
Being involved in this study, there is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. 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. You may stop your participation in this study at any time.

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

EMLA Cream may cause some, all or none of the side effects listed below.
<u>More likely</u>

- Temporary paleness (occurs in 37% of instances), redness (occurs in 30% of instances), and/or swelling of the skin at the site of application. This would not affect your doctor's ability to complete the procedure.
- Temporary topical irritation or skin reaction. There is a <1% chance of rash that could affect the biopsy being performed.
- Accidental trauma to the skin with scratching or rubbing while the skin is still numb at the site of medication application.

<u>Less Likely</u>

- Blue mouth or nail beds indicating methemoglobinemia, a condition that causes too little oxygen to be delivered to cells, and can be lead to a medical emergency in rare cases.
- If you are taking certain medications for irregular heartbeat, there is a risk of the medicines acting in combination resulting in abnormal heart rhythms or low blood pressure.

There is a risk of topical reaction at the site of application of the topical anesthesia. This would result in being unable to perform the vulvar biopsy during clinic and would necessitate a return clinic visit after the irritated area has resolved.

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Lidocaine injection may cause some, all, or none of the side effects listed below.

More likely

- Numbness, tingling at the site of injection
- Redness, paleness at the site of injection
- Accidental trauma to the skin with scratching or rubbing while the skin is still numb at the site of medication application

Less Likely

- Lightheadedness, ear ringing, dizziness
- Decreased heart rate or low blood pressure
- allergic reactions that may include itching, hives, swelling of the face, hands, mouth, or throat
- Blue mouth or nail beds indicating methemoglobinemia: a condition that causes too little oxygen to be delivered to cells, and can be lead to a medical emergency in rare cases
- If you are taking certain medications for irregular heartbeat, there is a risk of the medicines acting in combination resulting in abnormal heart rhythms or low blood pressure

For those of reproductive potential: Being a part of this study while pregnant presents minimal risk of harming the pregnancy. Pregnancy testing is not routinely performed prior to vulvar biopsy in clinic. You are not required to have a pregnancy test or any specific birth control method before or after the study is performed.

For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
You do not have to participate in this research study if you do not want to. You may choose to use either of these medications prior to your procedure. Please talk to your doctor about these and perhaps other options.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct benefit to you but this cannot be guaranteed.". If you are in the EMLA cream group, you may consider it a benefit that you will not receive an injection for anesthesia. We hope that in the future the information learned from this study will benefit other people receiving vulvar biopsies in clinic.

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WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain procedures performed. Some of these procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results of the indicated procedure will be recorded in your medical record and will be reported to the research data office at Duke. Results of tests and studies done solely for this research study and not as part of your regular care will also be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you

would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Laura Havrilesky. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

There will be no additional costs to you as a result of being in this study.

WHAT ABOUT COMPENSATION?
Subjects will be offered a $20 check for time spent participating in the study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Laura Havrilesky at (919) 684-3765 during regular business hours and at (919) 970-1613 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you verbally notify the study staff during your clinic visit.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue.

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Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Laura Havrilesky at (919) 684-3765 during regular business hours and at (919) 970-1613 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____ _____
Signature of Subject Date Time

_____
Printed name of Subject

_____
Subject's Date of Birth

_____ _____ _____
Signature of Person Obtaining Consent Date Time

_____
Printed name of Person Obtaining Consent