Duke University Health System

Consent to Participate in a Research Study
ADULT
Transcutaneous electrical nerve stimulation for analgesia during outpatient endometrial biopsy

CONCISE SUMMARY

The purpose of this study is to see whether transcutaneous electrical nerve stimulation (or TENS) reduces pain during an endometrial biopsy. A TENS unit is an over-the-counter (available without a prescription), FDA approved device that sends low-level electrical impulses through the skin to reduce the amount of discomfort experienced during procedures. A TENS unit is low-risk and used in a lot of ways, including for chronic pain, after surgery, and during labor. Since there is no standard way of managing pain during an endometrial biopsy, this study will see whether TENS will help with pain.

Participating in the study may require some additional time in clinic to answer research-related questions. You will be asked to answer some questions about yourself (which will be combined anonymously) before and after the procedure, as well as rate your pain at different time points during the procedure.

The benefit in participating in this study is that your discomfort might be lower during and after the procedure. However, this benefit cannot be guaranteed. There is a small risk of a skin reaction from wearing the TENS pads.

If you are interested in participating in this study, please continue reading below.

You are being asked to take part in this research study because you require an endometrial biopsy. 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.

This study is being conducted by Dr. Laura Havrilesky and is funded by the Duke University Department of Obstetrics and Gynecology.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Havrilesky will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

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WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see whether a TENS unit will help with pain during an endometrial biopsy. A TENS unit is FDA-approved for chronic pain relief and as an additional treatment for post-surgery and post-traumatic pain problems. A TENS unit has also been used in an investigational way for post-procedure pain and labor pain. The word "investigational" means the device is still being tested in research studies for these indications (uses).
Endometrial biopsy is a common procedure to diagnose uterine cancer and pre-cancer. It is often done when someone has abnormal bleeding or a thickened uterine lining on an ultrasound or other scan. Some people find the procedure to be painful, and there is currently no standard way of managing pain during an endometrial biopsy. Some options include taking ibuprofen or Tylenol, using a numbing medicine (such as a lidocaine spray or injection) or taking misoprostol (tablet) to help soften the cervix. A TENS unit is a nonpharmacologic (non-drug) option that may have fewer side effects and help with pain during an endometrial biopsy.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 160 people will take part in this study at Duke University.

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.

You will be randomly assigned (like a flip of a coin) to either the "active" group (having the TENS unit working) or the "placebo" group (having the TENS unit not working) during the procedure. You have a 50% chance of having an active TENS unit. We cannot tell you what group you will be in, and your doctor will also not know what group you are in. The pads will be placed at the bottom of your back (where the nerves that control pain to your uterus are near) prior to the procedure. We will help you learn how to use the device prior to starting. Your doctor will then perform the endometrial biopsy procedure, and you will be asked to rate your pain at different time points. These include 1) insertion of the speculum, 2) placement of the tenaculum (the instrument to stabilize the cervix), 3) time of biopsy, 4) removal of speculum, 5) 5 minutes after the procedure, and 6) 15 minutes after the procedure.

You will be asked survey questions before and after the procedure. These will be combined anonymously. You will be asked some general information about yourself, medical history, your current pain levels and anxiety about the procedure. After the procedure you will be asked about your experience

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Participation in this study is voluntary. Choosing not to participate in this study will not lead to any penalty or loss of benefits. You can choose to stop the study at any point. If you do not sign this consent form, you will continue to receive care, but not as a part of this study. You may be offered an alternative pain option for the endometrial biopsy, depending on your provider.

HOW LONG WILL I BE IN THIS STUDY?

You will be enrolled only for the duration of the biopsy and completion of post-procedure survey. 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. Your biopsy results will be explained to you in the normal time frame.

WHAT ARE THE RISKS OF THE STUDY?

There is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. 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. The risks to the endometrial biopsy will be explained to you by your provider and they will be the same whether or not you decide to participate in this study. You should discuss these with the study doctor and your regular health care provider if you choose.

TENS unit may cause some, all or none of the side-effects listed below.

<u>More likely</u>

- Skin irritation

<u>Less Likely</u>

- Electrode burns

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

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, you may experience pain relief, but this cannot be guaranteed. We hope that in the future the information learned from this study will benefit other people who will need an endometrial biopsy.

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WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

Endometrial biopsy is a procedure that can be performed with or without pain medications. Instead of being in this study, you have the option to undergo endometrial biopsy using other alternatives to control pain. Please talk to your doctor about these and perhaps other options.

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, 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.

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.

Some information collected in research studies is maintained in your medical record. However, for this study that information will be inaccessible until the end of the study, unless your physician(s) decide that it is necessary for your care.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.
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

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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?

There are no additional costs to you for participating in this research study. 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.

WHAT ABOUT COMPENSATION?

There is no compensation provided for participation in this research 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. 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.

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 other than data needed to keep track of your withdrawal.

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

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

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.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

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
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time