Title of Research Study: ***Transcutaneous electrical nerve stimulation (TENS) for pain control during cervical dilator placement prior to dilation and evacuation: A randomized controlled trial***

Investigator: Leanne McCloskey, MD, MPH

Supported By: This research is supported by The Society of Family Planning Research Fund

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are having dilators placed prior to your dilation and evacuation procedure.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
The purpose of this study is to determine if TENS (Transcutaneous electrical nerve stimulation) is effective for pain control during dilator placement prior to dilation and evacuation procedure. Dilator placement for cervical preparation is a necessary aspect of the dilation and evacuation procedure, however given that no anesthesia is provided for this procedure, it is often the most uncomfortable aspect of the procedure. TENS has been used for pain relief since 1965, and is thought to release natural endorphins and block pain sensation for pain control. TENS devices are small, portable, inexpensive, and have few contraindications. Previous studies in the field of OB/GYN have shown that TENS can provide pain relief with minimal side effects. It has not been studied with dilator placement, and if effective could provide improved pain management for patients in the future.

How long will the research last and what will I need to do?
We expect that you will be in this research study for 24-36 hours.

You will be asked to use the TENS device or a placebo (“inactive”) device during dilator placement as instructed. You will then be asked to rate your pain. You will take the TENS

device home and will complete a pain log detailing pain in the hours between dilator placement and dilation and evacuation procedure. You will have the option of using the TENS device or prescribed conventional pharmacologic methods of pain management during that time. On the day of surgery you will be asked to complete another pain rating as well as a survey regarding satisfaction. You will then return the TENS device.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?
The main risk is that the TENS device does not improve pain control during dilator placement.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improved pain control during dilator placement and in the hours between dilator placement and dilation and evacuation.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Instead of being in this research study, you can opt for conventional pain control methods, including a paracervical injection of lidocaine and NSAIDs or narcotics for use at home.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

Leanne McCloskey, MD, MPH
675 N. St. Clair
Suite 14-200
Chicago, IL, 60611
312-926-8678

Ashley Turner, MD
675 N. St. Clair
Suite 14-200
Chicago, IL, 60611
312-926-8678

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- 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 participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect about 70 people will be in this research study

What happens if I say "Yes, I want to be in this research"?
If you consent to this research study, you will first be asked to complete a demographic information questionnaire. You will then be randomized to either active TENS or placebo TENS group. This randomization for the treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given either treatment. You will not be told which treatment you are getting, however your study doctor will know. You will have electrode pads placed on your lower abdomen. You will be asked to rate your baseline pain. The TENS device which will be used is the Chattanooga Primera TENS device. The placebo TENS is the same device, however has been modified to not transmit electricity to the electrode pads. The first program will be activated by research staff. This first program runs for one hour. This program will be started 5 minutes prior to speculum placement for routine dilator placement.

Following device initiation the dilator insertion process will begin. You will be instructed to increase the amplitude of the TENS as needed to improve analgesia without causing discomfort from the TENS during the dilator placement in the office. You will also receive standard pain control during the dilator placement procedure.

Following dilator placement you will be asked to rate your pain. You will then be given a pain log and instructed on how to fill it out at home. You will receive standard prescriptions for ibuprofen 600mg tablets (#20) and Norco 5/325 tablets (#12) regardless of study group. You will be instructed to use your TENS as needed until the following day using the same program. You will be given an instruction guide for the unit and numbers to call in case of emergency.

If a second set of dilators is needed, you will return 6 hours after the first set and will be asked to run the TENS unit in the same manner as with initial dilator placement. You will be asked to rate your pain with this insertion as well.

On the day of surgery you will be asked to bring your TENS unit and prescription pill bottles with you to the hospital. You will complete another pain score reporting highest level of pain between dilator placement and procedure. You will also be asked to complete a survery detailing satisfaction with the device. You will then return the device.

All research will be done at Northwestern Memorial Hospital in either the Family Planning Clinic or pre-operative area. No further follow up appointments will be required. The initial consultation is one hour in length regardless of study participation. The time spent in the pre-operative area is 90 mins regardless of study participation. No blood will be drawn for study purposes.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to:

1. Use the TENS device as instructed
2. Fill out pain log
3. Return TENS following study completion

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you agree, this data will be handled the same as research data.

Detailed Risks: Is there any way being in this study could be bad for me?
The physical risk of this study is that the active TENS may create a mildly uncomfortable sensation across your lower abdomen. You may also have an allergic reaction to the electrode pads. The risks with the placebo TENS are that you may have an allergic reaction to the electrode pads and that you will not receive pain relief from the device.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

What do I need to know about reproductive health and/or sexual activity if I am in this study?
There are no known risks to a pregnancy or fetus

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you.

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: Improved pain control during dilator insertion and in the hours between dilator insertion and dilation and evacuation procedure.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution. If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

A description of this clinical trial will be available at 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.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?
If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

HIPAA Authorization
We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Demographic information
- Results of physical examinations
- Medical history
- Surgical history
- Lab tests, or certain health information relating to pregnancy

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy

[except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the research study

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Leanne McCloskey, MD, MPH
Institution: Northwestern University, Feinberg School of Medicine
Department: Obstetrics and Gynecology
Address:
675 N. St. Clair
Suite 14-200
Chicago, IL, 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent