

A Randomized Controlled Trial of Transcutaneous Electrical Nerve Stimulation (TENS)
for Treatment of IUD Insertion Pain

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NCT06245655

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STUDY INFORMATION:

Study Title: A randomized controlled trial of transcutaneous electrical nerve stimulation for pain control during IUD insertion

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, Mount Sinai Beth Israel, Mount Sinai Union Square, Mount Sinai Morningside, Mount Sinai West

Lead Researcher (Principal Investigator): Lauren Kus, MD

Physical Address: 1 Gustave L Levy Place, New York, NY, 10029

Mailing Address: Department of Obstetrics, Gynecology, and Reproductive Science, Icahn School of Medicine at Mount Sinai, 1176 Fifth Ave, 9th Floor, New York, NY 10029

Phone: 646-877-6797

SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to investigate pain control options during IUD insertion. Currently, there is no standardized pain management method for this procedure despite the fact that many patients experience moderate pain with IUD insertion. We are investigating an over-the-counter non-pharmacologic pain management device that has been successfully and safely used to prevent pain in other gynecologic procedures. This device has not yet been studied for IUD insertion but may be a potential option to minimize pain.

This pain management device is a small, battery-powered device. It delivers signals through sticky pads placed on the skin that have wires that connect back to the device. The signal and connection from the device to the sticky pads facilitates pain management. You will not have to set up the device on your own for this study. A member of the study team will make sure the device is set up for you and that you are connected to the device by placing sticky pads on your lower back and abdomen before your IUD insertion procedure.

If you choose to take part, you will be asked to:

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- Provide informed consent
- Complete a baseline demographic survey
- Complete the PROMIS 10 Global Health questionnaire: PROMIS 10 is a validated survey that asks you to rate your physical, mental, and social health.
- Be randomized to receive or not receive transcutaneous electrical nerve stimulation during your procedure
- Answer questions about your pain level during IUD insertion
- Agree to have private information and study data stored in an encrypted database accessible only by the study team for the duration of the study

There are no costs associated with taking part in this study. You will be compensated for your time with a \$15 amazon gift card, which you will receive electronically via e-mail.

If you choose to take part, the main risks to you are adhesive reactions (such as skin irritation) from the device pads.

You may benefit from taking part in this research. A potential benefit is pain reduction during and/or after IUD insertion.

Instead of taking part in this research, you may still have your IUD insertion with standard pain control options in our clinic.

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

STUDY PARTICIPATION:

You may qualify to take part in this research study because you are having an IUD insertion.

Your participation in this research study is expected to last only today, the day of your IUD insertion procedure.

There are 98 people expected to take part in this research study across four sites within the Mount Sinai Health System.

Funds for conducting this research study are provided by the Society of Family Planning Research Fund.

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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.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

- All research activities will take place at the clinic on the day of your procedure
- You will complete a baseline survey and provide informed consent
- You will complete the PROMIS 10 Global Health questionnaire
- You will be randomized to either receive either the active or placebo device during your IUD insertion
 - Regardless of which group you are randomized to, the device pads will be applied to your abdomen and lower back prior to your procedure. Only patients randomized to the active treatment group will have the device turned on by the research staff. You will not know which group you are a part of.
- You will be asked to rate your pain at various timepoints during and after the IUD insertion procedure
- You will complete a post-procedure survey about your experience
- Participation in this study should require no more than 20 additional minutes on top of your already scheduled procedure time

Randomization

No one, not you, or anyone from your medical team or from the research team will be able to choose what group you are assigned to or whether or not you will receive transcutaneous electrical nerve stimulation. It will be by chance, like flipping a coin. You will have an equal chance of being given the active or placebo device. Neither you nor the Lead Researcher or your own doctor will know which treatment you are getting. If there is an emergency, they can get this information.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

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If "Yes", please indicate your preferred method of contact: (initial all that apply)

☐ Email ☐ Phone ☐ Letter ☐ Text

USE OF YOUR DATA AND/OR SAMPLES:

The researchers would like your permission to keep your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) to use or share in future studies. You can still be part of the study if you do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select 'No' each time.

(1) Will you allow the researchers to store your data and/or samples to use in future research studies?

Please initial your choice: Yes _____ No _____

If you select No, please stop here and move to the next section, '**Your Responsibilities If You Take Part in This Research**' section below."

If yes, please continue to the next question and tell us how your personal information, study data and/or samples may be used in future research studies.

(2) The researchers can store your data and/or samples in one of two ways:

- a) Anonymously (no one will know who the data and/or samples came from). If you choose this option, you can't change your mind. So, if you wanted to have your data and/or samples destroyed in the future, the team could not do it as they would not know which data and/or samples were yours.
- b) Linked to your identity (using a code that can show the information came from you personally). In this case you could ask for your data and/or samples to be destroyed in the future if you want that to happen.

How would you like your data and/or samples stored? Please initial **ONE** choice below:

I would like my data and/or samples stored anonymously _____

I would like my data and/or samples stored with a link to my identity through the use of a code _____

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(3) Do you give the researchers permission to keep the data and/or samples, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes _____ No _____

(4) Do you give the researchers permission to keep the data and/or samples indefinitely, so they could use them for future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes _____ No _____

(4.1) From time to time, researchers outside of medicine and related sciences would like to use data and/or samples. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your data and/or samples?

Please initial your choice: Yes _____ No _____

- a. If the future research in a different area can be done without having to know that the data and/or samples came from you personally, that will be done.
- b. If the future research in a different area requires that it is known specifically who the data and/or samples came from, then one of the following will be done:
 - I. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your data and/or samples is needed and what will be done with it. Your permission will be asked to use your data and/or samples in that research project.
 - II. If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical (for example, because you have moved), your data and/or samples may still be used. The Institutional Review Board (IRB) will be asked for permission to use the data and/or samples linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the data and/or samples will not be more than minimal risk to you or your privacy. The IRB is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

(5) Do you give permission to have your data and/or samples given **to other researchers**, including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?

Please initial your choice: Yes _____ No _____

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YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for answering survey questions before, during, and after your IUD insertion procedure.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this study, you will be paid \$15 in the form of an Amazon giftcard (sent to your email address) for your time and effort. *It can take up to 2 weeks to prepare and send you a gift card for study participation.*

POSSIBLE BENEFITS:

There is a chance this study may benefit you, but this is not guaranteed. Others may benefit from what researchers learn from the study. Possible benefits to you include: pain reduction during and/or after IUD insertion. Future benefits to others may include evidence to support new pain management strategies for IUD insertion.

POSSIBLE RISKS AND DISCOMFORTS:

- Physical risks (for example, skin irritation or burn at site of device pads)
- Psychological risks (for example, distress from survey questions)
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- Overall, risks are rarely expected. If any risk were to occur and require treatment, you will be referred to the appropriate location and provider for treatment.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

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ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you stop being in the research study, the research team may not remove information they have already placed in the study database, and may continue to use that data as part of this study. The research team may ask you whether they can continue to collect information from your medical record.

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your data withdrawn or labeled so that they will not be used in additional projects or shared. If your data has already been shared with researchers, those researchers will be asked to stop using them. However, if any data has already been shared without your identity or a linking code, it won't be possible to retrieve them. Data that has already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number 646-877-6797.

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DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at <http://icahn.mssm.edu/> where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?

PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this study, the research team at the hospital(s) involved in the research will collect your: name, address, telephone/fax numbers, birth date, clinic visit date, e-mail/internet protocol (IP) addresses, medical records number.

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, temperature, and pelvic exam (as would be performed for any IUD insertion).
- Completing the procedures, questionnaires and interviews explained in the description section of this consent.

Why is your PHI being used?

Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of

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this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

Who, outside Mount Sinai, might receive your PHI?

As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- Other collaborating research center(s) and their associated research/clinical staff who are working with the researchers on this project: Mount Sinai Hospital, Mount Sinai Beth Israel, Mount Sinai Morningside, Mount Sinai West, Yale School of Medicine and other sites available on request. Yale School of Medicine is one of our study sites for this study. They are conducting the same study under a different lead researcher who is based at their institution. The Yale study team will use our research database for data collection for their patients. Since our research database will be shared with Yale, the information gathered by the Mount Sinai research team about you during your participation in this study might be accessible to the Yale study team. Our research partnership with Yale includes regular meetings to ensure protection of patient data across sites.

In all disclosures outside of Mount Sinai, you will not be identified by name, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

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For how long will Mount Sinai be able to use or disclose your PHI?

Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?

NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

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Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

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

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ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____ Signature of Participant	_____ Printed Name of Participant	_____ Date	_____ Time
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PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____ Signature of Consent Delegate	_____ Printed Name of Consent Delegate	_____ Date	_____ Time
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WITNESS SECTION:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ Signature of Witness	_____ Printed Name of Witness	_____ Date	_____ Time
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