Transcutaneous Electrical Nerve Stimulation (TENS) for Pain Control During Cervical Dilator Placement Prior to Dilation and Evacuation

ClinicalTrials.gov Identifier: NCT03868787

Recruitment Status : Not yet recruiting
First Posted : March 11, 2019
Last Update Posted : March 11, 2019

See Contacts and Locations

Sponsor:
Ashley Turner

Collaborator:
Society of Family Planning

Information provided by (Responsible Party):
Ashley Turner, Northwestern University

Study Details | Tabular View | No Results Posted | Disclaimer

How to Read a Study Record

Study Description

Go to

Brief Summary:
This study evaluates the use of Transcutaneous Electrical Nerve Stimulation (TENS) as a method of pain control during

osmotic dilator insertion prior to dilation and evacuation. Half the group will have an active TENS unit and half will have a sham or placebo TENS unit.

Condition or disease	Intervention/treatment	Phase
Pain Management	Device: TENS Device: Sham TENS	Not Applicable

Show Detailed Description

Study Design

Go to

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	70 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Single (Participant)
Masking Description:	The experimental group will have an active TENS unit - Chattanooga Primera - and the control group will have a sham TENS unit. The sham TENS will be the same unit without the true TENS electrical connections. The true TENS unit consists of the active unit and electrode pads connected to the unit via direct wires. The sham group will be given the active unit and have electrode pads placed but without wire connections. These participants will be told the device is a wireless device. They will also be told they may or may not feel sensation from the TENS. This will allow the device to be powered on and run in the same manner as the active group, but will not allow for electrical transmission between the unit and electrodes
Primary Purpose:	Treatment
Official Title:	Transcutaneous Electrical Nerve Stimulation (TENS) for Pain Control During Cervical Dilator Placement Prior to Dilation and Evacuation: A Randomized Controlled Trial
Estimated Study Start Date :	March 15, 2019
Estimated Primary Completion Date :	June 1, 2020
Estimated Study Completion Date :	July 1, 2020

Resource links provided by the National Library of Medicine

NIH NLM

MedlinePlus related topics: Non-Drug Pain Management

U.S. FDA Resources

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: Active TENS The active TENS unit consists of the active unit and electrode pads connected to the unit via direct wires. The program that will be used is a high frequency (80Hz) program that runs for an hour in duration. It will be initiated 5 minutes prior to speculum placement. Participants will be instructed to increase the amplitude of the current as needed to provide analgesia but avoiding discomfort from the TENS stimulation	Device: TENS TENS units are small, inexpensive, portable, battery-powered devices which deliver mild, alternating electrical currents via electrodes positioned on the skin near the anticipated dermatomal distribution of pain.
Sham Comparator: Sham TENS The sham TENS will be the same unit without the true TENS electrical connections. The sham group will be given the active unit and have electrode pads placed but without wire connections. These participants will be told the device is a wireless device. They will also be told they may or may not feel sensation from the TENS. This will allow the device to be powered on and run in the same manner as the active group, but will not allow for electrical transmission between the unit and electrodes	Device: Sham TENS Non-active TENS unit

Outcome Measures

Go to

Primary Outcome Measures :

1. Pain following dilator placement [Time Frame: within 5 mins after dilator placement procedure]

   Self-reported pain on 100mm VAS immediately following dilator placement

Secondary Outcome Measures :

1. Pain at dilator exchange [Time Frame: within 5 mins after dilator exchange procedure]

   Self-reported pain on 100mm VAS immediately following dilator exchange (if applicable)

2. Interval pain [Time Frame: 5 mins after dilator placement to 36 hours after dilator placement]

   Self-reported highest level of pain between dilator placement and D&E on 100mm VAS

3. Adjunctive pain medications [Time Frame: 5 mins after dilator placement to 36 hours after dilator placement]

   Number and type of adjunctive pain medications used (Norco and ibuprofen), self-reported and confirmed with pill bottles

4. Patient satisfaction [Time Frame: 24-36 hours after dilator placement, immediately prior to D&E]

   Patient satisfaction with device based on 4 questions with 5 point Likert scale

Eligibility Criteria

Go to

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	Female
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

1. Women ≥ 18 years of age
2. Gestational age between 14 weeks and 23 weeks 6 days
3. Willing and able to sign an informed consent in English
4. No contraindications to TENS

Exclusion Criteria:

1. Incarceration
2. Preterm Premature Rupture of Membranes or evidence of intra-amniotic infection

3. Presence of implanted cardiac device
4. Lack of sensation to touch on area of electrode placement
5. Prior TENS use
6. Opioid dependence

Contacts and Locations

Go to

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03868787***

Contacts

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Contact: Leanne McCloskey, MD, MPH	312-926-8678	legriffi@nm.org

Locations

United States, Illinois

Northwestern Center for Family Planning and Contraception — **Not yet recruiting**
Chicago, Illinois, United States, 60611
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Sponsors and Collaborators

Ashley Turner

Society of Family Planning

Investigators

Principal Investigator: Leanne McCloskey, MD, MPH Northwestern University

Study Documents (Full-Text)

Documents provided by Ashley Turner, Northwestern University:

Study Protocol and Statistical Analysis Plan [PDF] December 4, 2018

Informed Consent Form [PDF] January 24, 2019

More Information

Go to

Publications:

Binder P, Gustafsson A, Uvnäs-Moberg K, Nissen E. Hi-TENS combined with PCA-morphine as post caesarean pain relief. Midwifery. 2011 Aug;27(4):547-52. doi: 10.1016/j.midw.2010.05.002. Epub 2010 Jul 7.

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Johnson MI, Paley CA, Howe TE, Sluka KA. Transcutaneous electrical nerve stimulation for acute pain. Cochrane Database Syst Rev. 2015 Jun 15;(6):CD006142. doi: 10.1002/14651858.CD006142.pub3. Review.

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Mercier RJ, Liberty A. Intrauterine lidocaine for pain control during laminaria insertion: a randomized controlled trial. Contraception. 2014 Dec;90(6):594-600. doi: 10.1016/j.contraception.2014.07.008. Epub 2014 Jul 23.

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Soon R, Tschann M, Salcedo J, Stevens K, Ahn HJ, Kaneshiro B. Paracervical Block for Laminaria Insertion Before Second-Trimester Abortion: A Randomized Controlled Trial. Obstet Gynecol. 2017 Aug;130(2):387-392. doi: 10.1097/AOG.0000000000002149.

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post-partum uterine contraction pain during breast-feeding: a randomized clinical trial. J Obstet Gynaecol Res. 2014 May;40(5):1317-23. doi: 10.1111/jog.12345. Epub 2014 Apr 21.

Vance CG, Dailey DL, Rakel BA, Sluka KA. Using TENS for pain control: the state of the evidence. Pain Manag. 2014 May;4(3):197-209. doi: 10.2217/pmt.14.13. Review.

Responsible Party:	Ashley Turner, Co-investigator, Northwestern University
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Other Study ID Numbers:	STU00209157
First Posted:	March 11, 2019 Key Record Dates
Last Update Posted:	March 11, 2019
Last Verified:	March 2019

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	Yes
Device Product Not Approved or Cleared by U.S. FDA:	No
Pediatric Postmarket Surveillance of a Device Product:	No
Product Manufactured in and Exported from the U.S.:	No

TO TOP

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