Gabapentin for Pain Control After Osmotic Dilator Insertion and Prior to D&E Procedure: a Randomized Controlled Trial (GABA)

ClinicalTrials.gov Identifier: NCT03080493

Recruitment Status: Recruiting
First Posted: March 15, 2017
Last Update Posted: June 29, 2018

See **Contacts and Locations**

Sponsor:
University of California, Davis

Collaborator:
Society of Family Planning

Information provided by (Responsible Party):
University of California, Davis

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:

Women having abortion procedures between 15 weeks 0 days and 23 weeks 6 days gestational age on the day of their procedure commonly have dilators placed in their cervix overnight before the abortion procedure. The dilators are put in during a pelvic exam in the clinic and after women go home they

expand slowly overnight to open the cervix before the abortion procedure the next day. This can be a painful experience and health care providers often give women different kinds of pain medicine to help them.

The investigators are interested in whether a medicine called gabapentin, which is a non-narcotic medicine, could help. Gabapentin is approved by the U.S. Food and Drug Administration (FDA) for prevention of seizures and for treating nerve pain and doctors are also using it to decrease pain for people having surgical procedures.

The main goals of our study are to learn about:

1. Women's pain experience with dilators in their cervix overnight before the abortion procedure
2. How well gabapentin works to decrease women's pain while they have the dilators in their cervix

Women who enroll in the study will get a dose of either gabapentin or placebo (a pill with no medicine in it) before their dilators are placed in the clinic. The medication they get (gabapentin or placebo) will be chosen by chance, like flipping a coin. Neither the women in the study nor the doctors giving them the medication will know which medication they receive so the investigators can learn about their pain without being influenced by knowing which medication they take. Doctors will be able to find out which medication women got if there is an emergency or if it changes their medical care.

The investigators will communicate with women in real time overnight by text messaging to see how much pain they are having in the moment and how much pain medicine they are taking.

The investigators hypothesize that women who receive gabapentin will have a smaller increase in their pain with the dilators than women who receive placebo (a pill with no medicine in it).

The investigators' findings will help doctors understand women's pain experience with dilators better and possibly provide a new way of treating pain with gabapentin.

Condition or disease	Intervention/treatment	Phase
Abortion, Induced Cervical Preparation Pain	Drug: Gabapentin 600mg Drug: Placebo oral capsule Drug: acetaminophen/codeine and ibuprofen	Phase 4

Detailed Description:

The investigators have planned a double-blind randomized controlled trial of repeated doses of gabapentin compared to placebo for pain management during the time after dilator insertion and prior to D&E the subsequent day.

- Participants will receive gabapentin 600 mg or placebo prior to dilator insertion
- Pain scores will be measured via numeric rating scale (NRS) at baseline and 5 minutes after last dilator insertion while the participant is in clinic

- Additional pain scores, side effects (specifically dizziness and sedation), and additional analgesic use will be obtained by text message while the patient is home at 2 hours, 4 hours, and 8 hours after time of dilator insertion
- Subjects will take a second dose of study drug (either gabapentin 600 mg or placebo, concordant with their initial medication) at 8 hours after their first dose
- Final pain score, side effect, and analgesic use assessment will occur upon presentation to the pre-operative are for D&E the subsequent day

There will be no change in standard insertion of osmotic dilators (hygroscopic dilators only with Lidocaine 20mL cervical anesthesia), or provision of home analgesic medications (ibuprofen and acetaminophen with codeine in our practice).

The investigators hypothesize that women who receive gabapentin will report a smaller increase in pain from baseline at 8 hours after dilator placement compared to women receiving placebo.

Study Design

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Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	120 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	Randomized placebo controlled trial, stratified block randomization based on prior vaginal parity (vaginal parity - yes or no). Goal of even distribution of prior vaginal parity between gabapentin and placebo groups as may impact osmotic dilator pain experience
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	Gabapentin for Pain Control After Osmotic Dilator Insertion and Prior to D&E Procedure: a Randomized Controlled Trial
Actual Study Start Date:	March 20, 2017
Estimated Primary Completion Date:	December 2018
Estimated Study Completion Date:	December 2018

Resource links provided by the National Library of Medicine

Drug Information available for: Codeine Gabapentin Gabapentin enacarbil

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: Gabapentin Gabapentin 600 mg PO - first dose in clinic prior to osmotic dilator placement, second dose 8 hours later (at home) Will receive standard regimen of acetaminophen/codeine and ibuprofen to take as needed for pain overnight	Drug: Gabapentin 600mg Gabapentin 600 mg PO (two total doses, thereby lasting duration while osmotic dilators are in place) Other Name: Neurontin Drug: acetaminophen/codeine and ibuprofen Over the counter analgesic medications Other Names: • Tylenol-Codeine No. 3 • Advil
Placebo Comparator: Placebo oral capsule Matched placebo Will receive standard regimen of acetaminophen/codeine and ibuprofen to take as needed for pain overnight	Drug: Placebo oral capsule Packaged identical to gabapentin dosing Other Name: Carboxymethyl cellulose Drug: acetaminophen/codeine and ibuprofen Over the counter analgesic medications Other Names: • Tylenol-Codeine No. 3 • Advil

Outcome Measures

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Primary Outcome Measures:

1. Mean change from baseline in NRS pain score at 8 hours after dilator insertion [Time Frame: 8 hours after insertion of last osmotic dilator]

   Pain score based on numeric rating scale; Baseline obtained prior to study drug ingestion/dilator insertion. NRS pain score obtained via text message.

Secondary Outcome Measures :

1. Mean change from baseline in NRS pain score at 5 minutes after last dilator insertion [Time Frame: 5 minutes after insertion of last osmotic dilator]

   Pain score based on numeric rating scale; Baseline obtained prior to study drug ingestion/dilator insertion. NRS pain score obtained in person before subject leaves clinic appointment.

2. Mean change from baseline in NRS pain score at 2 hours after dilator insertion [Time Frame: 2 hours after insertion of last osmotic dilator]

   Pain score based on numeric rating scale; Baseline obtained prior to study drug ingestion/dilator insertion. NRS pain score obtained via text message.

3. Mean change from baseline in NRS pain score at 4 hours after dilator insertion [Time Frame: 4 hours after insertion of last osmotic dilator]

   Pain score based on numeric rating scale; Baseline obtained prior to study drug ingestion/dilator insertion. NRS pain score obtained via text message.

4. Mean change from baseline in NRS pain score at time of presentation for D&E procedure (day following dilator insertion) [Time Frame: Time of presentation for D&E (day after dilator insertion)]

   Pain score based on numeric rating scale; Baseline obtained prior to study drug ingestion/dilator insertion. NRS pain score obtained in person upon presentation for D&E procedure.

5. use of standard pain medication (acetaminophen/codeine and ibuprofen) between both groups [Time Frame: Collected between each subject contact (2 hours, 4 hours, 8 hours after dilator insertion and at time of presentation for D&E procedure)]

   Subject account of how many tabs of acetaminophen/codeine and ibuprofen they have taken (both are standard medications given for PRN use after dilator insertion)

Eligibility Criteria

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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:	No

Criteria

Inclusion Criteria:

- 15 weeks 0 days gestational age - 23 weeks 5 days gestational age at time of dilator insertion
- Able to read and write in English
- Active cell phone with text messaging capability
- Ride home from dilator insertion clinic appointment

Exclusion Criteria:

- Current use of gabapentin or pregabalin
- Allergy to gabapentin, acetaminophen, codeine, or ibuprofen
- Self reported renal disease (severe impaired renal function)
- Self reported current or chronic narcotic use (typical daily use)
- Women with any issue that, in the opinion of the investigator, would interfere with study participation or generating accurate study data

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03080493***

Contacts

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Sponsors and Collaborators

University of California, Davis

Society of Family Planning

Investigators

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More Information

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Publications:

Yan PZ, Butler PM, Kurowski D, Perloff MD. Beyond neuropathic pain: gabapentin use in cancer pain and perioperative pain. Clin J Pain. 2014 Jul;30(7):613-29. doi: 10.1097/AJP.0000000000000014. Review.

Rose MA, Kam PC. Gabapentin: pharmacology and its use in pain management. Anaesthesia. 2002 May;57(5):451-62. Review.

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.

Responsible Party:	University of California, Davis
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Other Study ID Numbers:	987072
First Posted:	March 15, 2017 Key Record Dates
Last Update Posted:	June 29, 2018
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Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No

Keywords provided by University of California, Davis:
Abortion
Osmotic dilators
Gabapentin
Text message

Additional relevant MeSH terms:

Acetaminophen	Cyclooxygenase Inhibitors
Ibuprofen	Enzyme Inhibitors
Gabapentin	Molecular Mechanisms of Pharmacological Action
Codeine	Anticonvulsants
gamma-Aminobutyric Acid	Antiparkinson Agents
Carboxymethylcellulose Sodium	Anti-Dyskinesia Agents
Analgesics, Non-Narcotic	Calcium Channel Blockers
Analgesics	Membrane Transport Modulators
Sensory System Agents	Anti-Anxiety Agents
Peripheral Nervous System Agents	Tranquilizing Agents
Physiological Effects of Drugs	Central Nervous System Depressants
Antipyretics	Psychotropic Drugs
Anti-Inflammatory Agents, Non-Steroidal	Excitatory Amino Acid Antagonists
Anti-Inflammatory Agents	Excitatory Amino Acid Agents
Antirheumatic Agents	Neurotransmitter Agents