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Effect of Paracervical Block Volume on Pain Control for Dilation and Curettage

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ClinicalTrials.gov Identifier: NCT03736681

Recruitment Status : Recruiting
First Posted : November 9, 2018
Last Update Posted : April 17, 2019

See **Contacts and Locations**

Sponsor:
University of California, San Diego

Collaborator:
University of California, Los Angeles

Information provided by (Responsible Party):
Bonnie Crouthamel, University of California, San Diego

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

Study Description

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Brief Summary:

The investigators are conducting a study on pain control for dilation and curettage (D&C). Participants are eligible to enroll if they are a planning to have a D&C in a participating clinic. The investigators are studying how different ratios of medication to liquid affect pain when injected around the cervix. Both potential methods use the same dose of medication, though researchers would like to know which one works better. To be in this study, participants must be over the age of 18 with an early pregnancy loss or undesired pregnancy measuring less than 12 weeks gestation undergoing D&C while awake in clinic.

Condition or disease	Intervention/treatment	Phase
Abortion Early Abortion, Missed Abortion, Spontaneous Abortion in First Trimester	Drug: 40cc buffered 0.5% lidocaine with 2 units of vasopressin paracervical block Drug: 20cc 1% lidocaine with 2 units of vasopressin paracervical block	Phase 1

Detailed Description:

Dilation and Curettage (D&C) is often performed in the first trimester for surgical abortion and management of miscarriage and can be painful for patients before and after the procedure. Most procedures are performed while the patient is awake or with minimal sedation in the clinic setting, and a key component of pain control is the paracervical block, or injecting lidocaine into the tissue around the cervix. A paracervical block with 20cc of 1% buffered lidocaine has been proven to provide superior pain control than a sham paracervical block. However, many providers often use similar doses of lidocaine in a higher volume to improve pain control. At University of California, San Diego (UCSD) and University of California, Los Angeles (UCLA), some providers routinely use a 20cc of 1% buffered lidocaine block and some routinely use a 40cc of 0.5% buffered lidocaine block. This practice has not been studied in a randomized controlled trial. The purpose of this study is to compare pain control during D&C with a 20cc 1% buffered lidocaine with vasopressin paracervical block compared to a 40cc 0.5% buffered lidocaine with vasopressin paracervical block.

An inclusion criterion for this study is that patients must specifically be referred to family planning clinics at UCSD and UCLA for an in-clinic D&C. Therefore, the D&C is a required procedure for both study groups. The only difference in care between the study groups will be which paracervical block they receive.

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	120 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment

Intervention Model Description:	This is a double center, randomized, 2-arm (1:1), single blinded clinical trial comparing pain control at the time of cervical dilation with two different paracervical blocks in women undergoing D&C in the first trimester for either surgical abortion or miscarriage management.
Masking:	Single (Participant)
Primary Purpose:	Treatment
Official Title:	Assessing the Effect of Paracervical Block Volume on Pain Control for Dilation and Curettage: a Randomized Controlled Trial
Actual Study Start Date :	October 29, 2018
Estimated Primary Completion Date :	July 31, 2019
Estimated Study Completion Date :	August 30, 2019

Resource links provided by the National Library of Medicine

Drug Information available for: Lidocaine hydrochloride Lidocaine Vasopressin

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: 40cc 40c buffered 0.5% lidocaine with 2 units of vasopressin paracervical block with dilation and curettage under minimal sedation	Drug: 40cc buffered 0.5% lidocaine with 2 units of vasopressin paracervical block Women undergoing D&C in the first trimester for either surgical abortion or miscarriage management will receive 40cc buffered 0.5% lidocaine with 2 units of vasopressin paracervical block before cervical dilation.
Active Comparator: 20cc 20cc 1% lidocaine with 2 units of vasopressin paracervical block with dilation and curettage under minimal sedation	Drug: 20cc 1% lidocaine with 2 units of vasopressin paracervical block Women undergoing D&C in the first trimester for either surgical abortion or miscarriage management will be randomly assigned to receive 20cc 1% lidocaine with 2 units of vasopressin paracervical block before cervical dilation.

Outcome Measures

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Primary Outcome Measures :

1. Pain during cervical dilation [Time Frame: immediate]

   Distance (mm) from the left of the 100-mm Visual Analogue Scale (VAS) scale (reflecting magnitude of pain) recorded at time of cervical dilation. Pain will be assessed using a 100 mm visual analogue scale with the anchors 0 = none, 100 mm = worst imaginable. We will also assess pain at various time points (including secondary outcomes) immediately upon completion of the respective step.

Secondary Outcome Measures :

1. Pain level at other time points (baseline, speculum placement, block placement, uterine aspiration, 10 minutes post-procedure, overall) [Time Frame: during 1 day of clinic visit]

   pain at different time points

2. Patient Satisfaction [Time Frame: during 1 day of clinic visit]

   How did the paint compare to the expected pain? What could have been better?

3. Adverse events [Time Frame: immediate]

   side effects at time of paracervical block placement

4. Survey of provider performing procedure [Time Frame: during 1 day of clinic visit]

   Clinical questions about the patient and the procedure

Eligibility Criteria

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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 over the age of 18 presenting to University of California, San Diego (UCSD) and University of California, Los Angeles (UCLA)
2. Undesired pregnancy or missed abortion < 11 weeks 6 days gestation
3. Must speak English or Spanish
4. Desire surgical termination of pregnancy or management of miscarriage in clinic

Exclusion criteria:

1. Women with a diagnosis of inevitable or incomplete abortion
2. Desire for general anesthesia or IV sedation
3. Chronic pain conditions
4. Any medical comorbidities that are a contraindication to performing the procedure in the clinic setting
5. Allergy to or refusal of ketorolac, oral Versed, or a paracervical block
6. If they have taken any pain medications the day of presentation to clinic
7. If they have taken Misoprostol the day of presentation to clinic

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): ***NCT03736681***

Contacts

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Locations

United States, California

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Principal Investigator: Bonnie Crouthamel, MD

Sponsors and Collaborators

University of California, San Diego

University of California, Los Angeles

More Information

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Responsible Party:	Bonnie Crouthamel, Principal Investigator, University of California, San Diego
ClinicalTrials.gov Identifier:	NCT03736681 History of Changes
Other Study ID Numbers:	180999
First Posted:	November 9, 2018 Key Record Dates
Last Update Posted:	April 17, 2019
Last Verified:	April 2019

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
Product Manufactured in and Exported from the U.S.:	No

Additional relevant MeSH terms:

Abortion, Spontaneous
Abortion, Missed
Pregnancy Complications
Lidocaine
Vasopressins
Arginine Vasopressin
Anesthetics, Local
Anesthetics
Central Nervous System Depressants
Physiological Effects of Drugs
Sensory System Agents
Peripheral Nervous System Agents
Anti-Arrhythmia Agents
Voltage-Gated Sodium Channel Blockers
Sodium Channel Blockers
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Hemostatics
Coagulants
Vasoconstrictor Agents
Antidiuretic Agents
Natriuretic Agents