Oral Sedation During Cervical Dilator Placement (OSDI)

ClinicalTrials.gov Identifier: NCT03202550

Recruitment Status : Recruiting
First Posted : June 28, 2017
Last Update Posted : January 29, 2018

See **Contacts and Locations**

Sponsor:
Johns Hopkins University

Collaborator:
Society of Family Planning

Information provided by (Responsible Party):
Johns Hopkins University

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

Study Description

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Brief Summary:

This will be a randomized, double-blind, placebo-controlled trial involving 2 arms. It will be comparing the effects of placebo compared to 1 mg oral lorazepam/5 mg oral oxycodone on pain scores during cervical dilator placement prior to dilation and evacuation (D&E).

Condition or disease	Intervention/treatment	Phase
Oral Sedation and Cervical Dilator Pain	Drug: Oxycodone and Lorazepam (Active Comparator) Drug: Placebo Comparator	Phase 4

Detailed Description:

Potential participants will be first introduced to the study via routine intake call. Participants will be identified at the participant's office visits to the Johns Hopkins' Women's Center for Family Planning. If a patient desires D&E for a second trimester pregnancy, the patient will first receive standard counseling. Only after providing written informed consent for the procedure will the patients be screened for eligibility in the study. If the patient is eligible the participant will be asked by a member of the research team if the patient is interested in participating. If the patient is, the study will be explained to the participant and written consent will be obtained after participant is given the opportunity to have all questions answered.

The study is randomized, double-blind, placebo-controlled trial involving 2 arms. Participants will first complete a survey to collect demographic data.

Participants in both arms will receive the institution's current standard analgesia for cervical dilator placement. In addition to this standard regimen, participants will be randomized to receive either: (1) a dose of two oral placebo pills, or (2) 1mg of oral lorazepam with 5 mg of oral oxycodone prior to cervical dilator placement.

Study Design

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Study Type : Interventional (Clinical Trial)
Estimated Enrollment : 60 participants
Allocation: Randomized

Intervention Model:	Parallel Assignment
Intervention Model Description:	Randomized controlled trial
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Masking Description:	The participant, provider, and nursing staff will be blinded to the intervention. The pharmacy will prepare the treatment drugs and placebos.. Randomization will be stratified by gestational age (>= 20 weeks or <20 weeks) and the randomization allocation sequence will be computer-generated with a random number generator by a statistician. The pharmacist will be aware of the randomization sequence and will dispense the drugs as appropriate, while keeping track of which arms participants were randomized to.
Primary Purpose:	Treatment
Official Title:	Oral Sedation During Cervical Dilator Placement: A Randomized Controlled Trial
Actual Study Start Date :	June 28, 2017
Estimated Primary Completion Date :	September 1, 2018
Estimated Study Completion Date :	October 1, 2018

Resource links provided by the National Library of Medicine NIH NLM

Drug Information available for: Oxycodone Oxycodone hydrochloride Lorazepam

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Placebo Comparator: Placebo Arm Two oral placebo pills (microcrystalline cellulose capsules)	Drug: Placebo Comparator Placebo oral pills
Active Comparator: Active Drug Arm: Lorazepam and Oxycodone	Drug: Oxycodone and Lorazepam (Active Comparator)

1 mg of oral lorazepam and 5 mg of oral oxycodone (also encased in microcrystalline cellulose capsules)	Oxycodone and Lorazepam Other Names: • Oral Oxycodone • Oral Lorazepam • Ativan • OxyIR • Roxicodone

Outcome Measures

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Primary Outcome Measures :

1. Cervical dilator placement pain as assessed by VAS on a tablet device [Time Frame: Immediately after the last dilator is placed, up to 1 minute.]

   Compare pain scores on a 100 mm visual analog scale (VAS) (anchors 0=no pain; 100=worst pain ever)

Secondary Outcome Measures :

1. Procedure Time for Dilator Placement [Time Frame: Time of speculum placement to the time of last dilator placement, up to 20 minutes.]

   Assess procedure time for cervical dilator placement, comparing 2 arms

2. Number of dilators inserted [Time Frame: After speculum removed, up to 30 minutes]

   Assess whether desired number (or more than desired) of dilators were successfully inserted, comparing 2 arms. Up to 13 dilators

3. Dilator Pain Experience after Placement [Time Frame: 2 hours after dilator placement]

Compare pain scores on a 10 point numeric rating scale (NRS) (anchors 0=no pain; 10=worst pain ever) after dilator placement via text messaging

4. Dilator Pain Experience after Placement [Time Frame: 4 hours after dilator placement]

   Compare pain scores on a 10 point numeric rating scale (NRS) (anchors 0=no pain; 10=worst pain ever) after dilator placement via text messaging

5. Dilator Pain Experience after Placement [Time Frame: 8 hours after dilator placement]

   Compare pain scores on a 10 point numeric rating scale (NRS) (anchors 0=no pain; 10=worst pain ever) after dilator placement via text messaging

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 to 50 Years (Adult)
Sexes Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Women aged 18-50 years
- English speaking
- With an intrauterine pregnancy (either viable or non-viable) between the gestational ages of 17w0d and 23w6d
- Have a support person present with them
- Have a cell phone capable of text messaging (optional)

Exclusion Criteria:

- Non-English-speaking
- Taking a daily benzodiazepine or opiate
- Have a known allergy or contraindication to NSAIDs, opiates, or benzodiazepines

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): ***NCT03202550***

Contacts

Contact: Jessica K Lee, MD 410-550-8506 jlee574@jhmi.edu

Locations

United States, Maryland

Johns Hopkins' Women's Center for Family Planning **Recruiting**
Baltimore, Maryland, United States, 21224
Contact: Jessica K Lee, MD jlee574@jhmi.edu

Sponsors and Collaborators

Johns Hopkins University

Society of Family Planning

More Information

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Publications:

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.

Soon, R. T., M.; Salcedo. J.; Kaneshiro, B., Paracervical block to decrease pain with second-trimester laminaria insertion: a randomized controlled trial. Contraception 2016, 94 (4), 389.

Wong CY, Ng EH, Ngai SW, Ho PC. A randomized, double blind, placebo-controlled study to investigate the use of conscious sedation in conjunction with paracervical block for reducing pain in termination of first trimester pregnancy by suction evacuation. Hum Reprod. 2002 May;17(5):1222-5.

Wiebe E, Podhradsky L, Dijak V. The effect of lorazepam on pain and anxiety in abortion. Contraception. 2003 Mar;67(3):219-21.

Responsible Party:	Johns Hopkins University
ClinicalTrials.gov Identifier:	NCT03202550 History of Changes
Other Study ID Numbers:	IRB00117627
First Posted:	June 28, 2017 Key Record Dates
Last Update Posted:	January 29, 2018
Last Verified:	January 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Yes

Plan Description: The study plans to share placebo data (without PHI) with colleagues at University of California Davis at the end of the study. A Memorandum of Understanding will be created prior to sharing (MOU) and data will be shared across a secure server.

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.:	Yes

Keywords provided by Johns Hopkins University:

Oral Sedation

Lorazepam

Oxycodone

Additional relevant MeSH terms:

Oxycodone

Lorazepam

Analgesics, Opioid

Narcotics

Central Nervous System Depressants

Physiological Effects of Drugs

Analgesics

Sensory System Agents

Peripheral Nervous System Agents

Anticonvulsants

Antiemetics

Autonomic Agents

Gastrointestinal Agents

Hypnotics and Sedatives

Anti-Anxiety Agents

Tranquilizing Agents

Psychotropic Drugs

GABA Modulators

GABA Agents

Neurotransmitter Agents

Molecular Mechanisms of Pharmacological Action