LINK: https://clinicaltrials.gov/ct2/show/NCT01330459

Hydrocodone For Pain Control in First Trimester Surgical Abortion

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT01330459

Recruitment Status : Completed
First Posted : April 7, 2011
Results First Posted : April 26, 2019
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Sponsor:
Elizabeth Micks
Collaborator:
Planned Parenthood Federation of America
Information provided by (Responsible Party):
Elizabeth Micks, Oregon Health and Science University

- **Study Details**

Study Description

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Brief Summary:

The purpose of this study is to determine whether preoperatively administered hydrocodone/acetaminophen (HC/APAP) reduces pain during a first trimester surgical abortion.

Condition or disease	Intervention/treatment	Phase
Pain	Drug: Hydrocodone/acetaminophenDrug: PlaceboDrug: IbuprofenDrug: LorazepamDrug: Lidocaine	Phase 4

Detailed Description:

The investigators plan to conduct a double-blinded randomized placebo-controlled trial of 120 women undergoing elective first trimester surgical abortion. These women will be premedicated with either two tabs of 5/350 hydrocodone/acetaminophen or 2 tabs of a placebo. All subjects will receive ibuprofen and lorazepam preoperatively and a PCB. This study will examine the incremental benefit of HC/APAP over this standard medication regimen. Randomization will be stratified into two groups. Subjects less than 8 weeks gestation will comprise the early gestational age group. Subjects between 8 weeks 0 days and 10 weeks 6 days will comprise the late gestational age group. The investigators will be assessing patient perception of pain, nausea, satisfaction, and anxiety at multiple points during the clinic visit using 100-mm visual analogue scales (VAS).

Study Design

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Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	121 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Triple (Participant, Care Provider, Investigator)

Primary Purpose:	Treatment
Official Title:	An Evaluation of Hydrocodone/Acetaminophen for Pain Control in First Trimester Surgical Abortion
Study Start Date :	February 2011
Actual Primary Completion Date :	October 2011
Actual Study Completion Date :	October 2011

Resource links provided by the National Library of Medicine
Drug Information available for: Acetaminophen Hydrocodone Hydrocodone bitartrate Hycodan

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: Hydrocodone/acetaminophen Subject will receive hydrocodone/acetaminophen 45-90 minutes prior to	Drug: Hydrocodone/acetaminophen Administration of 2 tablets 5/325mg hydrocodone/acetaminophen 45-90 procedure.

Arm	Intervention/treatment
abortion procedure. Subject will also recieve ibuprofen, lorazepam, and lidocaine 45-90 minutes prior to abortion procedure.	Other Name: Vicodin Drug: Ibuprofen 800 mg oral ibuprofen Drug: Lorazepam 2 mg oral lorazepam Drug: Lidocaine 20 ml 1% buffered lidocaine, injected
Placebo Comparator: Placebo Subject will receive placebo 45-90 minutes prior to abortion procedure. Subject will also recieve ibuprofen, lorazepam, and lidocaine 45-90 minutes prior to abortion procedure.	Drug: Placebo Administration of 2 tablets methylcellulose (placebo) 45-90 minutes prio Drug: Ibuprofen 800 mg oral ibuprofen Drug: Lorazepam 2 mg oral lorazepam Drug: Lidocaine 20 ml 1% buffered lidocaine, injected

Outcome Measures

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Primary Outcome Measures :

1. Patient Perception of Pain [Time Frame: At time of uterine aspiration (baseline)]

To determine whether HC/APAP, given in addition to a standard regimen of ibuprofen, lorazepam, and PCB, affects patient pain perception at the time of uterine aspiration, as measured by distance (mm) from the left of the 100 mm visual analog scale (VAS). The number 0 indicates no pain, and 100 indicates worst pain imaginable.

Secondary Outcome Measures :

1. Patient Perception of Pain During Cervical Dilation [Time Frame: During procedure (approximately 45-90 min after hydrocodone/acetaminophen or placebo, and within 5 minutes of procedure starting)]

   Distance (mm) from the left of the 100 mm VAS scale (VAS anchors: 0 = none, 100 mm = worst imaginable) recorded after cervical dilation

2. Satisfaction With Pain Control [Time Frame: 30 minutes after completion of the procedure (which started 45-90 minutes after study drug administration)]

   Distance (mm) from the left of the 100 mm VAS (VAS anchors: 0 = unsatisfied, 100 mm = very satisfied) recorded 30 minutes after completion of the procedure.

3. Postoperative Nausea [Time Frame: 30 minutes after completion of the procedure (which started 45-90 minutes after study drug administration)]

   To assess whether HC/APAP is associated with nausea, measured on the 100 mm VAS, recorded 30 minutes postoperatively. VAS anchors: 0 indicates no pain, and 100 indicates worst pain imaginable.

4. Need for Additional Intraoperative and/or Postoperative Pain Medication [Time Frame: 30 minutes after completion of the procedure (which started 45-90 minutes after study drug administration)]

   To assess need for additional intraoperative and/or postoperative pain medication

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 65 Years (Adult, Older Adult)
Sexes Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Aged 18 years or older
- Voluntarily requesting surgical pregnancy termination
- Pregnancy with intrauterine gestational sac up to 10 weeks 6 days gestation, dated by ultrasound
- Eligible for suction curettage

- English or Spanish speaking
- Good general health
- Able and willing to give informed consent and agree to terms of the study

Exclusion Criteria:

- Gestational ages 11 weeks or more
- Incomplete abortion
- Premedication with misoprostol
- Use of any opioid medication within the past 7 days
- Use of heroin within the past 7 days
- Requested opioids or IV sedation prior to start of the procedure
- Patients who refuse ibuprofen or lorazepam
- Contraindications or allergies to HC/APAP, lidocaine, ibuprofen, or lorazepam
- Significant medical problem necessitating inpatient procedure
- Adnexal mass or tenderness on pelvic exam consistent with pelvic inflammatory disease
- Known hepatic disease

Contacts and Locations

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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): ***NCT01330459***

Locations

United States, Oregon

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