Evaluation of Oral Midazolam in First-trimester Surgical Abortions

ClinicalTrials.gov Identifier: NCT01830881

Recruitment Status : Completed
First Posted : April 12, 2013
Results First Posted : June 14, 2017
Last Update Posted : June 25, 2018

Sponsor:
Oregon Health and Science University

Information provided by (Responsible Party):
Lisa Bayer, MD MPH, Oregon Health and Science University

Study Description

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Brief Summary:
The purpose of this study is to determine the level of pain, anxiety and side effects that women experience with a surgical abortion and the effect that the anti-anxiety medication, midazolam, might have when used along with ibuprofen and a paracervical block (PCB) instead of the standard pain treatment of only ibuprofen and a PCB.

Condition or disease	Intervention/treatment	Phase
Pain	Drug: Midazolam	Phase 4

Anxiety Nausea	Drug: Ibuprofen Other: Placebo-Cherry syrup Drug: Lidocaine	

Detailed Description:
Women in the study will be randomized to receive either midazolam or placebo. Every participant will still receive the standard oral medications for pain (ibuprofen) as well as an injection of numbing medicine (lidocaine) near the cervix (PCB). The co-primary outcomes are patient perception of anxiety and pain with uterine aspiration reported on a 100 mm visual analogue scale (VAS). Secondary outcomes include reported anxiety and pain at time points before, during, and after the procedure, as well as subject satisfaction with anxiety and pain control and overall abortion experience. Due to the dose-dependent anterograde amnesic effect of midazolam, we will also investigate the effects on memory and recall, which has not previously been studied. In addition, we will also collect data on side effects frequently associated with oral midazolam such as nausea and sleepiness. Women will also be responsible for completing a one-page survey 1-3 days after the procedure visit and return it by mail using a pre-addressed and stamped envelope.

Study Design

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Study Type :
Interventional (Clinical Trial)

Actual Enrollment :
124 participants

Allocation:
Randomized

Intervention Model:
Parallel Assignment

Masking:
Double (Participant, Investigator)

Primary Purpose:
Treatment

Official Title:
An Evaluation of Oral Midazolam for Anxiety and Pain in First-trimester Surgical Abortion: a Randomized Controlled Trial

Study Start Date :
April 2013

Actual Primary Completion Date :
December 2013

Actual Study Completion Date :
January 2014

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Anxiety

Drug Information available for: Lidocaine Ibuprofen Ibuprofen sodium Ibuprofen lysine Midazolam Midazolam maleate Midazolam hydrochloride Midol

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Placebo Comparator: placebo-cherry syrup and ibuprofen 5 mL oral placebo-cherry syrup and 800 mg oral ibuprofen 30-60 minutes prior to procedure 20 mL injection 1% lidocaine without epinephrine	Drug: Ibuprofen 800 mg oral ibuprofen 30-60 minutes prior to procedure Other Name: Motrin Other: Placebo-Cherry syrup 5 mL oral placebo-cherry syrup 30-60 minutes prior to procedure Other Name: placebo cherry syrup Drug: Lidocaine injection of 20 mL 1% lidocaine without epinephrine Other Name: lidocaine injection

Arm	Intervention/treatment
Active Comparator: Midazolam and ibuprofen 5 mL oral midazolam oral syrup (2 mg/mL) and 800 mg oral ibuprofen 30-60 minutes prior to procedure 20 mL injection 1% lidocaine without epinephrine	Drug: Midazolam 5 mL oral midazolam oral syrup (2 mg/mL) 30-60 minutes prior to procedure Other Name: Versed Drug: Ibuprofen 800 mg oral ibuprofen 30-60 minutes prior to procedure Other Name: Motrin Drug: Lidocaine injection of 20 mL 1% lidocaine without epinephrine Other Name: lidocaine injection

Outcome Measures

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Primary Outcome Measures :

1. Subject Perception of Pain and Anxiety During Uterine Aspiration [Time Frame: at time of uterine aspiration (30-60 minutes after premedication)]

   Subjects will be asked to rate anxiety and pain at the time of uterine aspiration by marking along a 100 mm Visual Analog Scale, with 0mm being No Pain/Anxiety and 100mm being Worst Imaginable Pain/Anxiety

Secondary Outcome Measures :

1. Subject Anticipated Perception of Pain and Anxiety During Uterine Aspiration at Baseline [Time Frame: Baseline (upon entry into study)]

   Subjects will be asked to rate their anticipated anxiety and pain at the time of uterine aspiration by marking along a mm Visual Analog Scale, with 0mm being No Pain/Anxiety and 100mm being Worst Imaginable Pain/Anxiety

2. Subject Perception of Pain and Anxiety Upon Entering Procedure Room [Time Frame: upon entering procedure room (30-60 minutes after premedication)]

Subjects will be asked to rate anxiety and pain upon entering procedure room by marking along a mm Visual Analog Scale, with 0mm being No Pain/Anxiety and 100mm being Worst Imaginable Pain/Anxiety

3. Subject Perception of Pain and Anxiety Post Procedure [Time Frame: 30 minutes post operatively]

   Subjects will be asked to rate anxiety and pain 30 minutes post-operatively by marking along a mm Visual Analog Scale, with 0mm being No Pain/Anxiety and 100mm being Worst Imaginable Pain/Anxiety

4. Subject Perception of Anxiety With Patient Positioning Procedure [Time Frame: prior to starting pelvic exam (30-60 minutes after premedication)]

   Subjects will be asked to rate anxiety prior to starting pelvic exam by marking along a mm Visual Analog Scale, with 0mm being No Anxiety and 100mm being Worst Imaginable Anxiety

5. Subject Perception of Pain During Cervical Dilation [Time Frame: with cervical dilation (30-60 minutes after premedication)]

   Subjects will be asked to rate pain at the time of cervical dilation by marking along a mm Visual Analog Scale, with 0mm being No Pain and 100mm being Worst Imaginable Pain

6. State-Trait Anxiety Inventory for Anxiety at Baseline [Time Frame: Baseline (upon entry into study)]

   To measure the mean State-Trait Anxiety Inventory (STAI) Form Y-1 for anxiety. State anxiety items include: "I am tense; I am worried" and "I feel calm; I feel secure." Trait anxiety items include: "I worry too much over something that really doesn't matter" and "I am content; I am a steady person." Each type of anxiety has its own 4-point scale of 20 different questions that are scored. The 4-point scale for S-anxiety is as follows: 1.) not at all, 2.) somewhat, 3.) moderately so, 4.) very much so. The 4-point scale for T-anxiety is as follows: 1.) almost never, 2.) sometimes, 3.) often, 4.) almost always. Scores range from 20 to 80, with higher scores indicate greater anxiety. State anxiety items and Trait anxiety items were each summed in assessment to provide two total scores for each participant, a State anxiety score and a Trait anxiety score. Mean and standard deviation of total scores for each group are reported.

7. Patient Satisfaction With Pain and Anxiety 30 Minutes Postoperatively [Time Frame: 30 minutes post-operatively]

   To assess whether oral midazolam is associated with differences in overall patient satisfaction with pain and anxiety control and abortion experience at 30 min postoperatively as measured by a mm Visual Analog Scale with 0mm being Not At All Satisfied and 100mm being Very Satisfied

8. Subject Satisfaction With Pain and Anxiety 1-3 Days Post Procedure [Time Frame: 1-3 days post-operatively]

   To assess whether oral midazolam is associated with differences in overall patient satisfaction with pain and anxiety control and abortion experience at 1-3 days postoperatively as measured by a mm VAS with 0mm being Not At All Satisfied and 100mm being Very Satisfied

9. Subject Extent of Amnesia Using Amnesia Score [Time Frame: 30 minutes postoperatively]

   To assess the extent of amnesia 30 min postoperatively as measured by ability to recall procedure using 4-point scale (0 = unable to recall any proportion of the procedure, 1 = able to recall and describe some portions of the procedure, but overall has minimal recall of the procedure, 2 = able to recall and describe most of the procedure, but admits to inability to recall some portion of the procedure, 3 = able to recall and describe the entire procedure).

10. Subject Extent of Amnesia [Time Frame: 1-3 days postoperatively]

    To assess the extent of amnesia 1-3 days postoperatively as measured by 100mm Visual Analog Scale with 0mm being Remember Nothing and 100mm being Remember Everything.

11. Subject Extent of Sedation [Time Frame: 30-60 minutes after premedication]

    Subject extent of sedation 30-60 minutes after premedication, just prior to procedure as measured by the 6-point Ramsay Scale (1 = patient anxious agitated, or restless; 2 = patient cooperative, oriented, and tranquil; 3 = patient asleep, responds to commands only; 4 = patient asleep, responds to gentle shaking, light glabellar tap, or loud auditory stimulus; 5 = patient asleep, responds to noxious stimuli such as firm nail bed pressure; 6 = patient asleep, has no response to firm nail bed pressure or other noxious stimuli)

12. Subject Vital Signs (Heart Rate) [Time Frame: intraoperatively (30-60 minutes after premedication)]

    Subject heart rate will be assessed for the duration of the procedure

13. Subject Vital Signs (Heart Rate) 30 Minutes Postprocedure [Time Frame: 30 minutes postoperatively]

    Subject vital signs (heart rate) will be assessed 30 minutes postoperatively

14. Subject Nausea 30 Minutes Postprocedure [Time Frame: 30 minutes postoperatively]

    Subject nausea will be assessed 30 minutes postoperatively using a 100mm Visual Analog Scale with 0mm being None and 100mm being Worst Imaginable

15. Subject's Correct Identification of Receiving Midazolam or Placebo [Time Frame: 30 minutes postoperatively]

    Number of patient's who could correctly determine if they received study drug or placebo when asked

16. Subject Vital Signs (Oxygenation Saturation) [Time Frame: intraoperatively (30-60 minutes after premedication)]

    Subject oxygenation status will be assessed for the duration of the procedure

17. Subject Vital Signs (Oxygenation Saturation) 30 Minutes Postprocedure [Time Frame: 30 minutes postoperatively]

    Subject vital signs (oxygenation saturation) will be assessed 30 minutes postoperatively

18. Subject Sleepiness 30 Minutes Postprocedure [Time Frame: 30 minutes postoperatively]

    Subject sleepiness will be assessed 30 minutes postoperatively using a 100mm Visual Analog Scale with 0mm being None and 100mm being Worst Imaginable

19. Number of Participants With Need for Additional Postoperative Pain Medication [Time Frame: 30 minutes postoperatively]

    Subjects will be assessed 30 minutes postoperatively for need of additional pain medications.

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 between 6 0/7 and 10 6/7 weeks gestation, dated by ultrasound
- Eligible for suction aspiration
- English or Spanish speaking
- Good general health
- Able and willing to give informed consent and agree to terms of the study
- Have assistance home; no driving for 24 hours

Exclusion Criteria:

- - Gestational ages 11 0/7 weeks or more
- Gestational age less than 6 0/7 weeks
- Incomplete abortion
- Premedication with misoprostol
- Use of narcotic pain or anti-anxiety medication within past 24 hours
- Use of heroin or methadone within last 3 months
- Chronic alcoholism or alcohol intoxication within past 24 hours
- Requested narcotics or Intravenous sedation (prior to randomization)
- Allergic reaction or allergy to cherry/cherry flavoring or lidocaine or non-steroidal anti-inflammatory drugs (NSAIDs)
- Allergic reaction or sensitivity to benzodiazepines including hyperactive or aggressive behavior (paradoxical reaction)
- Medical problem necessitating inpatient procedure
- Untreated acute cervicitis or pelvic inflammatory disease
- Known acute narrow-angle glaucoma
- Weighing less than 100 lb (45 kg)

- Use of potent medications interfering with microsomal metabolism within past 48 hours (carbamazepine (Tegretol), cimetidine (Tagamet), diltiazem (Cardizem), erythromycin, fluconazole (Diflucan), itraconazole (Sporanox), ketoconazole (Nizoral), phenobarbital, phenytoin (Dilantin), nelfinavir, ranitidine (Zantac), rifampin (Rifadin), ritonavir (Norvir), saquinavir, verapamil (Calan))

Contacts and Locations

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT01830881***

Locations

United States, Oregon

Planned Parenthood Columbia Willamette
Portland, Oregon, United States, 97206

Sponsors and Collaborators

Oregon Health and Science University

Investigators

Principal Investigator: Lisa Bayer, MD Oregon Health and Science University

More Information

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Bayer LL, Edelman AB, Fu R, Lambert WE, Nichols MD, Bednarek PH, Miller K, Jensen JT. An Evaluation of Oral Midazolam for Anxiety and Pain in First-Trimester Surgical Abortion: A Randomized Controlled Trial. Obstet Gynecol. 2015 Jul;126(1):37-46. doi: 10.1097/AOG.0000000000000913.

Responsible Party:

Lisa Bayer, MD MPH, MD, Oregon Health and Science University

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NCT01830881 History of Changes

Other Study ID Numbers:

OHSU IRB 9064

First Posted:

April 12, 2013 Key Record Dates

Results First Posted:

June 14, 2017

Last Update Posted:

June 25, 2018

Last Verified:

June 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

No

Keywords provided by Lisa Bayer, MD MPH, Oregon Health and Science University:

pain
anxiety
surgical abortion
midazolam
benzodiazepine

Additional relevant MeSH terms:

Anxiety Disorders
Mental Disorders
Ibuprofen
Lidocaine
Epinephrine
Midazolam
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
Adjuvants, Anesthesia
Hypnotics and Sedatives
Anti-Anxiety Agents
Tranquilizing Agents
Psychotropic Drugs
Anesthetics, Intravenous
Anesthetics, General
GABA Modulators
GABA Agents
Neurotransmitter Agents
Anti-Inflammatory Agents, Non-Steroidal
Analgesics, Non-Narcotic
Analgesics