Paracervical Block in First Trimester Surgical Abortions

Information source: Johns Hopkins University
ClinicalTrials.gov processed this data on August 23, 2015
Link to the current ClinicalTrials.gov record.

Condition(s) targeted: Pain; Surgical Abortion

Intervention: lidocaine (Drug); ketorolac and lidocaine (Drug)

Phase: Phase 2/Phase 3

Status: Completed

Sponsored by: Johns Hopkins University

Official(s) and/or principal investigator(s):
Johns Hopkins University, MD, Principal Investigator, Affiliation: Johns Hopkins University

Summary

The investigators primary objective is to study the analgesic effects of combined ketorolac and lidocaine in a paracervical block compared to preoperative ibuprofen followed by intra-operative paracervical block with lidocaine alone on women undergoing first trimester surgical abortions. The investigators hypothesize that women who receive a paracervical block of combined ketorolac and lidocaine will experience less pain during the procedure based on a visual analog scale (VAS) compared to those who receive preoperative ibuprofen and a paracervical block with lidocaine alone. This randomized, multi-site, placebo-controlled clinical trial will investigate the difference in perceived pain from first trimester surgical abortions using a paracervical block of combined ketorolac and lidocaine compared to preoperative ibuprofen and paracervical block with lidocaine alone. A total of fifty women who are seeking elective surgical abortions of intrauterine pregnancies less than 11 0/7 weeks' gestation will be recruited from Johns Hopkins Bayview Medical Center, Planned Parenthood of Maryland in Baltimore, Maryland and Planned Parenthood Columbia-Willamette in Portland, Oregon. Pain before, during, and after surgical abortion will be measured using a 100-mm VAS. The primary outcome of interest is the mean difference in pain level from preoperative baseline to time after cervical dilation comparing the treatment groups. If the investigators see greater pain reduction associated with the paracervical block of lidocaine and ketorolac, adoption of this regimen may improve pain management during first trimester surgical abortions. If combined ketorolac and lidocaine when administered as a paracervical block is proven to be efficacious, the need for additional analgesia in first trimester surgical abortions can be minimized.

Clinical Details

Official title: Paracervical Block With Ketorolac and Lidocaine in First Trimester Surgical Abortions

Study design: Allocation: Randomized, Endpoint Classification: Efficacy Study, Intervention Model: Parallel Assignment, Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Primary Purpose: Treatment

Primary outcome: Level of Pain During Specific Time Intervals Throughout D&C Procedure.

Secondary outcome:

Visual Analogue Scale Regarding Satisfaction Level

Reported Symptoms

Complications

Eligibility

Minimum age: 18 Years. Maximum age: 50 Years. Gender(s): Female.

Criteria:

Inclusion Criteria:

- age greater than or equal to 18 years

- English-speaking

- ability and willingness to sign the informed consent

- ability and willingness to comply with the terms of the study

- voluntary request for pregnancy termination

- ultrasound-confirmed singleton intrauterine pregnancy with an estimated gestational

age not exceeding 76 days (10 6/7 weeks) from the first day of the preceding menstrual cycle Exclusion Criteria:

- women who require or request sedation

- untreated acute cervicitis or pelvic inflammatory disease

- contraindications to lidocaine such as allergy to lidocaine, cardiac arrhythmia or

heart block, and porphyria

- allergic reaction or sensitivity to lorazepam or NSAIDs

- chronic NSAID use

- history of gastritis or gastric ulcer

- acute renal failure or chronic renal disease

- chronic liver disease

- history of bleeding diathesis

- chronic narcotic use

- current or past history of illegal drug use (excluding marijuana)

Locations and Contacts

Planned Parenthood Columbia-Willamette, Portland, Oregon 97239, United States

Additional Information

Starting date: January 2008
Last updated: October 15, 2014

Page last updated: August 23, 2015