Same-day Dilapan-S With Adjunctive Misoprostol (DAM)

ClinicalTrials.gov Identifier: NCT01818414

Recruitment Status : Terminated (Concerns for safety)
First Posted : March 26, 2013
Results First Posted : January 16, 2017
Last Update Posted : February 28, 2017

Sponsor:
University of Pittsburgh

Information provided by (Responsible Party):
Christy Boraas, University of Pittsburgh

Study Description

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Brief Summary:

Cervical preparation before second trimester dilation and evacuation (D&E) reduces risks and complications. Osmotic cervical dilators as well as prostaglandin analogues have been studied for cervical preparation. However, the optimal method for cervical preparation, especially for D&E procedures that occur on the same day as cervical preparation, is not known. This study will investigate misoprostol versus placebo as an adjunct to Dilapan-S for cervical preparation for same-day D&E between 16+0 and 20+6 weeks gestation.

HYPOTHESIS: Administration of 400 µg buccal misoprostol compared to placebo at least 3 hours prior to D&E as an adjunct to cervical preparation with Dilapan-S will decrease operative time for same-day D&E performed between 16+0 and 20+6 weeks.

Condition or disease	Intervention/treatment	Phase
Therapeutic Abortion	Drug: Misoprostol Drug: Folic Acid	Not Applicable

Detailed Description:

Dilation and evacuation (D&E) is commonly performed for second trimester abortions and management of second trimester intrauterine fetal demise (IUFD). Cervical preparation prior to second trimester D&E increases safety.

Osmotic cervical dilators and prostaglandin analogs are used widely for cervical preparation before second trimester D&E. Osmotic dilators are placed into the cervical canal, radially expand as they absorb moisture and decrease the risk of cervical injury during D&E. Laminaria tents are the most commonly used osmotic dilator for D&E cervical preparation but require N18 h to reach maximum diameter. Dilapan-S®, a synthetic osmotic cervical dilator, has a significant dilation effect 2 h after placement with the majority of expansion occurring in 4-6 h according to the manufacturer.

Misoprostol is the most commonly used pharmacologic cervical preparation for D&E with duration of action between 2 and 4 h after administration. Multiple studies demonstrate the safety of misoprostol before early second trimester abortion. One prospective and four retrospective studies suggest that same-day cervical preparation with Dilapan-S and/or misoprostol for second trimester D&E through 20 weeks is safe and effective. Misoprostol may be less effective when used alone compared to overnight osmotic dilators for cervical preparation later in the second trimester but has adjunctive benefit on cervical dilation and procedure time when used with overnight osmotic dilators between 16 and 24 weeks. The effect appears most pronounced at N19 weeks gestation. No prospective studies have been published examining misoprostol as an adjunct to osmotic dilators for cervical preparation for same-day D&E.

Administration of adjunctive misoprostol with Dilapan-S has the potential to effectively prepare the cervix and decrease operative time for same-day D&E. We compared cervical preparation with Dilapan-S with and without adjunctive buccal misoprostol for same-day D&E between 16 0/7 and 20 6/7 weeks gestation.

Study Design

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Study Type :

Interventional (Clinical Trial)

Actual Enrollment :

29 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Masking:

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose:

Treatment

Official Title:

Dilapan-S With Adjunctive Misoprostol for Same-day Second Trimester Dilation and Evacuation: A Randomized Trial

Study Start Date :

October 2013

Actual Primary Completion Date :

March 2014

Actual Study Completion Date :

April 2014

Resource links provided by the National Library of Medicine

MedlinePlus related topics: B Vitamins Folic Acid

Drug Information available for: Folic acid Vitamin B Complex Misoprostol

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Misoprostol Misoprostol 400 mcg buccal 3 hours prior to D&E as an adjunct to same-day Dilapan-S.	Drug: Misoprostol 400 mcg of buccal misoprostol, 3 hours prior to planned D&E Other Name: Cytotec

Arm	Intervention/treatment
Placebo Comparator: Folic Acid Folic acid 4 mg buccally 3 hours prior to D&E as an adjunct to same-day Dilapan-S	Drug: Folic Acid 4 mg of buccal folic acid, 3 hours prior to planned D&E Other Name: folate, vitamin M, vitamin B9

Outcome Measures

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Primary Outcome Measures :

1. Operative Time [Time Frame: Day 1 of the study]

   The primary outcome will be operative time. Operative time will be measured from initial passage of an instrument into the uterus to start the D&E. The end of operative time will be measured by the removal of the last instrument from the uterus to complete the D&E.

Secondary Outcome Measures :

1. Patient Pain [Time Frame: Day 1]

   Change in pain from baseline to immediately preoperatively using a 100-mm Visual Analogue Scale ("100-mm Visual Analogue Scale with 0 indicating "no pain" and 100 indicating "worst pain in my life")

2. Number of Participants With Postoperative Satisfaction [Time Frame: Day 1]

   Patient postoperative satisfaction with cervical preparation method

3. Number of Providers With Overall Satisfaction [Time Frame: Day 1]

   Provider overall satisfaction with cervical preparation

4. Complications [Time Frame: Day 1]

   Incidence of surgical complications related to D&E

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:

- Age greater than or equal to 18 years (no upper age limit)
- Gestational age between 16+0 and 20+6 weeks gestation on day of D&E with confirmation of gestational age by ultrasound
- Desires D&E for termination of pregnancy or for fetal demise
- Able to provide written informed consent
- Able to comply with study procedures
- English-speaking

Exclusion Criteria:

- Known allergy or contraindication to misoprostol
- Pregnancy with a multiple gestation
- Known bleeding disorder or current anticoagulation therapy (within one month of procedure)
- Active bleeding or hemodynamically unstable at enrollment
- Signs of chorioamnionitis or clinical infection at enrollment
- Signs of spontaneous labor or cervical insufficiency at enrollment

Contacts and Locations

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Locations

United States, Pennsylvania

Planned Parenthood of Western Pennsylvania
Pittsburgh, Pennsylvania, United States, 15213

Univeristy of Pittsburgh, Magee-Womens Hospital of UPMC
Pittsburgh, Pennsylvania, United States, 15213

Sponsors and Collaborators

University of Pittsburgh

Investigators

Principal Investigator: Principal Investigator, MD MPH University of Pittsburgh

More Information

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Publications of Results:

Boraas CM, Achilles SL, Cremer ML, Chappell CA, Lim SE, Chen BA. Synthetic osmotic dilators with adjunctive misoprostol for same-day dilation and evacuation: a randomized controlled trial. Contraception. 2016 Nov;94(5):467-472. doi: 10.1016/j.contraception.2016.05.008. Epub 2016 May 27.

Other Publications:

Edelman AB, Buckmaster JG, Goetsch MF, Nichols MD, Jensen JT. Cervical preparation using laminaria with adjunctive buccal misoprostol before second-trimester dilation and evacuation procedures: a randomized clinical trial. Am J Obstet Gynecol. 2006 Feb;194(2):425-30.

Goldberg AB, Drey EA, Whitaker AK, Kang MS, Meckstroth KR, Darney PD. Misoprostol compared with laminaria before early second-trimester surgical abortion: a randomized trial. Obstet Gynecol. 2005 Aug;106(2):234-41.

Newmann SJ, Dalve-Endres A, Diedrich JT, Steinauer JE, Meckstroth K, Drey EA. Cervical preparation for second trimester dilation and evacuation. Cochrane Database Syst Rev. 2010 Aug 4;(8):CD007310. doi: 10.1002/14651858.CD007310.pub2. Review.

Fox MC, Hayes JL; Society of Family Planning. Cervical preparation for second-trimester surgical abortion prior to 20 weeks of gestation. Contraception. 2007 Dec;76(6):486-95. Epub 2007 Nov 9.

Wilson LC, Meyn LA, Creinin MD. Cervical preparation for surgical abortion between 12 and 18 weeks of gestation using vaginal misoprostol and Dilapan-S. Contraception. 2011 Jun;83(6):511-6. doi: 10.1016/j.contraception.2010.10.004. Epub 2010 Dec 3.

Patel A, Talmont E, Morfesis J, Pelta M, Gatter M, Momtaz MR, Piotrowski H, Cullins V; Planned Parenthood Federation of America Buccal Misoprostol Waiver Group. Adequacy and safety of buccal misoprostol for cervical preparation prior to termination of second-trimester pregnancy. Contraception. 2006 Apr;73(4):420-30. Epub 2006 Jan 23.

Responsible Party:

Christy Boraas, MD, University of Pittsburgh

ClinicalTrials.gov Identifier:

NCT01818414 History of Changes

Other Study ID Numbers:

SFPRF-112778

First Posted:

March 26, 2013 Key Record Dates

Results First Posted:

January 16, 2017

Last Update Posted:

February 28, 2017

Last Verified:

January 2017

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

Undecided

Keywords provided by Christy Boraas, University of Pittsburgh:

Misoprostol administration & dosage
Abortion techniques
Abortion Induced methods
Dilatation and Curettage

Additional relevant MeSH terms:

Folic Acid
Vitamin B Complex
Misoprostol
Vitamins
Micronutrients
Nutrients
Growth Substances
Physiological Effects of Drugs
Abortifacient Agents, Nonsteroidal
Abortifacient Agents
Reproductive Control Agents
Anti-Ulcer Agents
Gastrointestinal Agents
Oxytocics
Hematinics