Comparing Misoprostol Alone to Dilapan With Misoprostol and Comparing Buccal to Vaginal Misoprostol

This study is ongoing, but not recruiting participants.

Sponsor:

Medstar Health Research Institute

Collaborator:

Society of Family Planning

Information provided by (Responsible Party):

Matthew Reeves, Medstar Health Research Institute

ClinicalTrials.gov Identifier:

NCT02363556

First received: February 3, 2015

Last updated: September 18, 2016

Last verified: September 2016

- Disclaimer
- How to Read a Study Record

Purpose

This randomized controlled trial will use a 2 by 2 factorial design to assess methods of cervical preparation prior to Dilation and Evacuations (D&Es) at 14 0/7 to 19 6/7 weeks gestational age. In total, 160 woman will be randomized to misoprostol alone or Dilapan with misoprostol and separately randomized to buccal or vaginal administration of 400-mcg misoprostol. A total of 80 women will receive 400-mcg misoprostol only (40 vaginal and 40 buccal). Another 80 women will have Dilapan inserted and then use misoprostol (40 vaginal and 40 buccal). Four to six hours later, the Dilation and Evacuation (D&E) procedure will be performed.

Condition	Intervention
Second Trimester Abortions	Procedure: Misoprostol administered vaginallyProcedure: Misoprostol administered buccallyProcedure: Misoprostol administered vaginally with DilapanProcedure: Misoprostol administered buccally with Dilapan

Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Factorial Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Factorial-Design Randomized Controlled Trial Comparing Misoprostol Alone to Dilapan With Misoprostol and Comparing Buccal to Vaginal Misoprostol for Same-Day Cervical Preparation Prior to Dilation & Evacuation

Resource links provided by NLM:

Drug Information available for: Misoprostol

U.S. FDA Resources

Further study details as provided by Matthew Reeves, Medstar Health Research Institute:

Primary Outcome Measures:

- Total procedure time [Time Frame: 4-6hrs]

  Total procedure time is defined as the time required for dilator insertion plus the D&E time.

Secondary Outcome Measures:

- D&E procedure time [Time Frame: 0-60 mins]
- Initial cervical dilation [Time Frame: 0-10 mins]

  Measured by the largest Hegar dilator accepted without resistance prior to the start of the procedure.

Enrollment:	160
Study Start Date:	January 2015
Estimated Study Completion Date:	June 2017
Primary Completion Date:	July 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Misoprostol Alone Subjects enrolled into this arm of the study will receive misoprostol 400-mcg only.	Procedure: Misoprostol administered vaginally Procedure: Misoprostol administered buccally
Experimental: Dilapan with Misoprostol Subjects enrolled into this arm of the study will receive Dilapan with 400-mcg misoprostol.	Procedure: Misoprostol administered vaginally with Dilapan Procedure: Misoprostol administered buccally with Dilapan

Detailed Description:

The primary objective of the study is to compare the efficacy of same-day 400-mcg misoprostol alone to same-day Dilapan with 400-mcg misoprostol for cervical preparation prior to D&E at 14 0/7

to 19 6/7 weeks. Patients will first be randomized to misoprostol alone or misoprostol-Dilapan, and then separately randomized to use the misoprostol buccally or vaginally.

The primary outcome measure is total procedure time. Secondary outcomes include D&E procedure time, initial cervical dilation (measured by the largest Hegar dilator accepted without resistance prior to the start of the procedure), patient-oriented outcomes (side effects of buccal and vaginal misoprostol), and patient acceptability and satisfaction.

The investigators have chosen a randomized controlled trial with a factorial design to be conducted at Washington Hospital Center and Planned Parenthood of Metropolitan Washington. A total up to 180 English speaking women will be enrolled in the study so that 160 will be randomized and receive study interventions. The study will enroll healthy women, over the age of 18, eligible for non-urgent D&E at 14 0/7 weeks to 19 6/7 weeks, confirmed by sonogram. The women will be randomized to receive either misoprostol alone or Dilapan with misoprostol. Women will then be randomized to receive 400-mcg of misoprostol either buccally or vaginally. Computer generated randomization will be utilized to assign treatment arms. Approximately 4-6 hours prior to procedure, women will be randomly assigned to one of the following treatment combinations:

1. Misoprostol 400-mcg vaginally
2. Misoprostol 400-mcg buccally
3. Dilapan insertion with 400-mcg misoprostol vaginally
4. Dilapan insertion with 400-mcg misoprostol buccally

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Sexes Eligible for Study: Female
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Healthy pregnant women
- 18 years of age or older
- Eligible for non-urgent Dilation and Evacuations at 14 0/7 - 19 6/7 weeks gestation confirmed by sonogram.

Exclusion Criteria:

- Women who do not speak English.
- Fetal demise

- Intolerance, allergy or contraindication to misoprostol or Dilapan.

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02363556

Locations

United States, District of Columbia

MedStar Washington Hospital Center
Washington, District of Columbia, United States, 20010

United States, Maryland

Planned Parenthood Metropolitan Washington
Silver Spring, Maryland, United States, 20910

Sponsors and Collaborators

Medstar Health Research Institute
Society of Family Planning

Investigators

Principal Investigator:	Dr. Matthew Reeves, MD MPH	MedStar Washington Hospital Center & Planned Parenthood of Metropolitan Washington
Study Chair:	Dr. Jamilah Shakir, MD MPH	Medstar Washington Hospital Center

More Information

Responsible Party:	Matthew Reeves, MD, Medstar Health Research Institute
ClinicalTrials.gov Identifier:	NCT02363556 History of Changes
Other Study ID Numbers:	2014-110
Study First Received:	February 3, 2015
Last Updated:	September 18, 2016

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Keywords provided by Matthew Reeves, Medstar Health Research Institute:

Cervical Dilation
Dilation and Evacuation
Misoprostol
Misoprostol-Dilapan
Abortion

Additional relevant MeSH terms:

Misoprostol
Abortifacient Agents, Nonsteroidal
Abortifacient Agents
Reproductive Control Agents
Physiological Effects of Drugs
Anti-Ulcer Agents
Gastrointestinal Agents
Oxytocics

ClinicalTrials.gov processed this record on August 15, 2017