

COVID-19 is an emerging, rapidly evolving situation.

Get the latest public health information from CDC: <https://www.coronavirus.gov>.

Get the latest research information from NIH: <https://www.nih.gov/coronavirus>.



Effects of Oxytocin on Bleeding Outcomes During Dilation and Evacuation



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: NCT02083809

[Recruitment Status](#) ⓘ : Completed

[First Posted](#) ⓘ : March 11, 2014

[Last Update Posted](#) ⓘ : May 15, 2018

Sponsor:

University of Hawaii

Collaborators:

Society of Family Planning

University of Washington

Information provided by (Responsible Party):

Bliss Kaneshiro, University of Hawaii

[Study Details](#)

[Tabular View](#)

[No Results Posted](#)

[Disclaimer](#)

[How to Read a Study Record](#)

Study Description

Go to

Brief Summary:

Currently, there is very little research to identify ways to decrease blood loss during D&E (dilation and evacuation) procedures. The objective is to determine whether routine use of intravenous oxytocin will improve bleeding outcomes at the time of D&E at 18-24-weeks gestation. To evaluate the hypothesis, investigators will perform a randomized, double-blinded,

placebo-controlled trial. The patient will be followed until discharged from the postoperative care unit during which time patient satisfaction, pain score and postoperative bleeding will be assessed.

| Condition or disease ⓘ | Intervention/treatment ⓘ | Phase ⓘ |
|--|---|-------------------------|
| Abortion | Drug: intravenous oxytocin | Not Applicable |
| Dilation and Evacuation | Drug: Intravenous Fluids and Electrolytes | |
| Hemorrhage | | |
| Blood Loss | | |

Study Design

Go to

[Study Type ⓘ](#) :

Interventional (Clinical Trial)

[Actual Enrollment ⓘ](#) :

166 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Masking:

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

Primary Purpose:

Treatment

Official Title:

A Randomized Double-blinded Controlled Trial Comparing Dilation and Evacuation Outcomes With and Without Oxytocin Use

[Actual Study Start Date ⓘ](#) :

October 2014

[Actual Primary Completion Date ⓘ](#) :

February 2018

[Actual Study Completion Date ⓘ](#) :

February 2018



Resource links provided by the National Library of Medicine



[MedlinePlus](#) related topics: [Bleeding](#)

[Drug Information](#) available for: [Oxytocin](#)

[U.S. FDA Resources](#)**Arms and Interventions**Go to

| Arm  | Intervention/treatment  |
|---|---|
| Placebo Comparator: Placebo 500ml saline or lactated ringer without oxytocin added | Drug: Intravenous Fluids and Electrolytes 500 ml of inert IV fluid |
| Active Comparator: Treatment group Intravenous oxytocin mixed with saline or lactated ringer | Drug: intravenous oxytocin 30 units of oxytocin added to 500ml of inert IV fluid (saline, lactated ringer) |

Outcome MeasuresGo to **Primary Outcome Measures**  :

1. Rate at which providers intervene to control blood loss during D&E procedures. [Time Frame: During surgical procedure]

Eligibility CriteriaGo to **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:

14 Years to 50 Years (Child, Adult)

Sexes Eligible for Study:

Female

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- Requesting pregnancy termination
- Intrauterine pregnancy at 18- to 24-weeks gestation
- Gestational-age to be confirmed by ultrasound
- Patients with fetal anomaly or intrauterine fetal demise that occurred at 18- to 24-weeks gestation
- Willing and able to understand and sign written informed consents in English or Spanish and comply with study procedures

Exclusion Criteria:

- Ultrasound findings suggestive of placenta accreta
- Patients requiring preoperative misoprostol

Contacts and Locations

Go to

Information from the National Library of Medicine



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): **NCT02083809***

Locations

United States, Hawaii

University of Hawaii

Honolulu, Hawaii, United States, 96826

United States, Washington

University of Washington

Seattle, Washington, United States, 98104

Sponsors and Collaborators

University of Hawaii

Society of Family Planning

University of Washington

More Information

Go to

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

[Whitehouse K, Tschann M, Soon R, Davis J, Micks E, Salcedo J, Savala M, Kaneshiro B. Effects of Prophylactic Oxytocin on Bleeding Outcomes in Women Undergoing Dilation and Evacuation: A Randomized Controlled Trial. Obstet Gynecol. 2019 Mar;133\(3\):484-491. doi: 10.1097/AOG.0000000000003104. Erratum in: Obstet Gynecol. 2019 Jun;133\(6\):1287-1288.](#)

Responsible Party:

Bliss Kaneshiro, Professor of Obstetrics & Gynecology, University of Hawaii

ClinicalTrials.gov Identifier:

[NCT02083809](#) [History of Changes](#)

Other Study ID Numbers:

OxyDE

First Posted:

March 11, 2014 [Key Record Dates](#)

Last Update Posted:

May 15, 2018

Last Verified:

May 2018

Additional relevant MeSH terms:

Hemorrhage
Dilatation, Pathologic
Pathologic Processes
Pathological Conditions, Anatomical
Oxytocin
Oxytocics
Reproductive Control Agents
Physiological Effects of Drugs