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**Effects of Oxytocin on Bleeding Outcomes During Dilation and Evacuation**

This study is currently recruiting participants. (see [Contacts and Locations](https://clinicaltrials.gov/ct2/show/study/NCT02083809#contacts))

Verified October 2014 by University of Hawaii

Sponsor:

University of Hawaii

Collaborators:

Society of Family Planning

University of Washington

Information provided by (Responsible Party):

Bliss Kaneshiro, University of Hawaii

ClinicalTrials.gov Identifier:

NCT02083809

First received: March 4, 2014

Last updated: October 1, 2014

Last verified: October 2014

  Purpose

Currently, there is very little research to identify ways to decrease blood loss during D&E (dilation and evacuation) procedures. Many practitioners use uterotonics, including oxytocin, to help minimize blood loss and decrease the risk of hemorrhage yet literature and physiological evidence to support this practice is scarce. The investigators objective is to determine whether routine use of intravenous oxytocin will affect 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 at two sites, at University of Hawaii and University of Washington, on subjects who present for D&E at 18-24-weeks over approximately a 14-month period. Standard D&E procedures will be performed by skilled surgeons in both the outpatient setting (in Washington) and the hospital operating room (in Hawaii). In addition to the procedure, investigators will also follow a standardized algorithm to manage excess, intraoperative bleeding and record blood loss. The patient will be followed only until discharged from the postoperative care unit during which time patient satisfaction, pain score and postoperative bleeding will be assessed. No additional follow-up after discharge home. Primary outcome will be the rate at which providers intervene to control blood loss during D&E procedures. Secondary outcomes evaluated will include measured blood loss, complication rates, procedure length, and postoperative pain and satisfaction.

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| [**Condition**](https://clinicaltrials.gov/ct2/help/conditions_desc) | [**Intervention**](https://clinicaltrials.gov/ct2/help/interventions_desc) |
| AbortionDilation and EvacuationHemorrhageBlood Loss | Drug: intravenous oxytocin |

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| Study Type: | Interventional  |
| Study Design: | Allocation: RandomizedEndpoint Classification: Efficacy StudyIntervention Model: Parallel AssignmentMasking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)Primary Purpose: Treatment |
| Official Title: | A Randomized Double-blinded Controlled Trial Comparing Dilation and Evacuation Outcomes With and Without Oxytocin Use |

Resource links provided by NLM:

[MedlinePlus](http://www.nlm.nih.gov/medlineplus/) related topics: [Bleeding](https://clinicaltrials.gov/ct2/bye/EQoPWw4lZX-i-iSxudhWudNzlXNiZip9m67PvQ7xzwhaLwS9pdhHz6hzu6SxlihLv.)

[Drug Information](http://druginfo.nlm.nih.gov/drugportal/drugportal.jsp) available for: [Oxytocin](https://clinicaltrials.gov/ct2/bye/3QoPWw4lZXcPSi7iedN6ZXNxvdDxuQ7Ju6c9cXcPSi7iEd-yWB7EZ6o35Q1yzB-VuQUgEscxkd789C-kxih90Q7O.)

[U.S. FDA Resources](https://clinicaltrials.gov/ct2/info/fdalinks)

Further study details as provided by University of Hawaii:

Primary Outcome Measures:

* Rate at which providers intervene to control blood loss during D&E procedures. [ Time Frame: During surgical procedure ] [ Designated as safety issue: No ]

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| Estimated Enrollment: | 166 |
| Study Start Date: | October 2014 |
| Estimated Primary Completion Date: | July 2015 (Final data collection date for primary outcome measure) |

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| [**Arms**](https://clinicaltrials.gov/ct2/help/arm_group_desc)  | [**Assigned Interventions**](https://clinicaltrials.gov/ct2/help/interventions_desc)  |
| Placebo Comparator: Placebo 500ml saline or lactated ringer without oxytocin added |  |
| 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) |

  Eligibility

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| Ages Eligible for Study:    | 14 Years to 50 Years |
| Genders Eligible for Study:    | Female |
| Accepts Healthy Volunteers:    | No |

Criteria

Inclusion Criteria:

* Age greater than 14-years
* 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

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.](https://clinicaltrials.gov/ct2/about-studies/learn)

Please refer to this study by its ClinicalTrials.gov identifier: NCT02083809

Contacts

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| Contact: Bliss Kaneshiro, MD, MPH | 808-372-7560 | blissk@hawaii.edu |  |
| Contact: Kate Whitehouse, DO | 201-650-1900 | kate.whitehouse@gmail.com |  |

Locations

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| United States, Hawaii |
| University of Hawaii | Recruiting |
| Honolulu, Hawaii, United States, 96826  |
| Contact: Kate Whitehouse, DO    201-650-1900    kate.whitehouse@gmail.com     |
| Contact: Bliss Kaneshiro, MD, MPH    808-372-7560    blissk@hawaii.edu     |
| Principal Investigator: Bliss Kaneshiro, MD, MPH           |
| Sub-Investigator: Kate Whitehouse, DO           |
| United States, Washington |
| University of Washington | Not yet recruiting |
| Seattle, Washington, United States, 98104  |
| Contact: Elizabeth Micks, MD, MPH       emicks@uw.edu     |
| Principal Investigator: Elizabeth Micks, MD, MPH           |

Sponsors and Collaborators

University of Hawaii

Society of Family Planning

University of Washington

  More Information

No publications provided

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| Responsible Party: | Bliss Kaneshiro, Professor of Obstetrics & Gynecology, University of Hawaii |
| ClinicalTrials.gov Identifier: | [NCT02083809](http://clinicaltrials.gov/show/NCT02083809)     [History of Changes](https://clinicaltrials.gov/ct2/archive/NCT02083809)  |
| Other Study ID Numbers: | OxyDE |
| Study First Received: | March 4, 2014 |
| Last Updated: | October 1, 2014 |
| Health Authority: | United States: Institutional Review Board |

Additional relevant MeSH terms:

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| OxytocinOxytocicsPharmacologic Actions | Physiological Effects of DrugsReproductive Control AgentsTherapeutic Uses |

ClinicalTrials.gov processed this record on March 25, 2015