**University of Hawaii – Patient Recruitment Details for Honolulu, HI abortion experiment**

**Original document found online at:** [**http://www.clinicalconnection.com/exp/FullStudyListing.aspx?studyID=371045&slID=18489293**](http://www.clinicalconnection.com/exp/FullStudyListing.aspx?studyID=371045&slID=18489293)

**Study Name: Effects of Oxytocin on Bleeding Outcomes During Dilation and Evacuation**

**(Honolulu, HI location)**

**View Clinical Trial (Medical Research Study)**

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

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| City: |  | Honolulu |
| State: |  | Hawaii |
| Zip Code: |  | 96826 |
| Conditions: |  | Abortion - Dilation and Evacuation - Hemorrhage - Blood Loss | |
| Purpose: |  | 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. | |
| Study Summary: |  |  | |
| 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 | |
| Study is Available At: |  | University of Hawaii Honolulu, Hawaii 96826 United States  ***Primary Contact:*** Kate Whitehouse, DO  *Site Status:* Recruiting | |

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| Original ID: |  | OxyDE | |
| NCT ID: |  | NCT02083809 | |
| Secondary ID: |  |  | |
| Study Acronym: |  |  | |
| Brief Title: |  | Effects of Oxytocin on Bleeding Outcomes During Dilation and Evacuation | |
| Official Title: |  | A Randomized Double-blinded Controlled Trial Comparing Dilation and Evacuation Outcomes With and Without Oxytocin Use | |
| ClinicalTrials.gov Link: |  | <http://clinicaltrials.gov/show/NCT02083809> | |
| Overall Status: |  | Recruiting | |
| Study Phase: |  | N/A | |
| Genders: |  | Female |
| Minimum Age: |  | 14 Years |
| Maximum Age: |  | 50 Years |
| Healthy Volunteers: |  | False |

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| Study Source: |  | University of Hawaii | |
| Oversight Authority: |  | United States: Institutional Review Board | |
| Oversight Has DMC: |  | True | |
| Reasons Why Stopped: |  |  | |
| Study Is FDA Regulated: |  | False | |
| Study Is Section 801: |  | False | |
| Has Expanded Access: |  | False | |
| Study Type: |  | Interventional | |
| Study Design: |  | Allocation: Randomized, Endpoint Classification: E | |
| Number of Arms: |  | 2 | |
| Number of Groups: |  | 0 | |
| Total Enrollment: |  | 166 | |
| Enrollment Type: |  | Anticipated | |
|  | | |
| **Overall Contact Information** | | |

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| **Primary Contact:** |  | **Bliss Kaneshiro, MD, MPH** 808-203-6500 [research@fpfellowshiphawaii.org](mailto:research@fpfellowshiphawaii.org?subject=NCT02083809,%20Effects%20of%20Oxytocin%20on%20Bleeding%20Outcomes%20During%20Dilation%20and%20Evacuation&body=I%20am%20interested%20in%20this%20clinical%20trial,%20I%20found%20it%20by%20searching%20for%20clinical%20trials%20at%20http://www.clinicalconnection.com.%20%20My%20contact%20information%20is:) |
| **Backup Contact:** |  | **Kate Whitehouse, DO** |

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| Study Dates |

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| **Start Date:** | |  | October 2014 |
| **Primary Completion Date:** | |  | July 2015 |
| **Primary Completion Type:** | |  | Anticipated |
| **Verification Date:** | |  | April 2015 |
| **Last Changed Date:** | |  | April 9, 2015 |
| **First Received Date:** | |  | March 4, 2014 |
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| Study Outcomes |

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| **Outcome Type:** |  | Primary Outcome |
| **Measure:** |  | Rate at which providers intervene to control blood loss during D&E procedures. |
| **Time Frame:** |  | During surgical procedure |
| **Safety Issues:** |  | False |

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| Study Interventions |

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| **Intervention Type:** | |  | Drug |
| **Name:** | |  | intravenous oxytocin |
| **Description:** | |  | 30 units of oxytocin added to 500ml of inert IV fluid (saline, lactated ringer) |
| **Arm Name:** | |  | Treatment group |
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| Study Arms |

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| **Study Arm Type:** |  | Active Comparator |
| **Arm Name:** |  | Treatment group |
| **Description:** |  | Intravenous oxytocin mixed with saline or lactated ringer |
| **Study Arm Type:** |  | Placebo Comparator |
| **Arm Name:** |  | Placebo |
| **Description:** |  | 500ml saline or lactated ringer without oxytocin added |

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| Study Agencies |

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| **Agency Class:** |  | Other |
| **Agency Type:** |  | Lead Sponsor |
| **Agency Name:** |  | University of Hawaii |
| **Agency Class:** |  | Other |
| **Agency Type:** |  | Collaborator |
| **Agency Name:** |  | Society of Family Planning |
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| There are no available Sample and Retention Information | | | |

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| There are no available Study Links |
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| There are no available Study References | |

Click here to see:

* [Clinical trials for Hemorrhage in Honolulu, Hawaii](http://www.clinicalconnection.com/hemorrhage-clinical-trials-in-honolulu-hawaii)

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| **Data Source:** |  | ClinicalTrials.gov |
| **Date Processed:** |  | June 03, 2015 |
| **Modifications to this listing:** |  | Only selected fields are shown, please use the link below to view all information about this clinical trial. |

If you would like to be contacted by the clinical trial representative please enter your contact information, then click I Am Interested In This Study

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| Full Name: | |
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| Email Address: | |
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| Confirm Email: | |
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| Daytime Phone (eg. 555-555-5555): | |
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| City: | |
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| State: | |
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| Zip Code: |
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| Best Time to Call: |
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