**University of Hawaii and University of Washington – Patient Recruitment details for Seattle, WA abortion experiment**

**Original document found online at:** [**http://www.clinicalconnection.com/exp/FullStudyListing.aspx?studyID=371045&slID=18489294**](http://www.clinicalconnection.com/exp/FullStudyListing.aspx?studyID=371045&slID=18489294)

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

**(Seattle, WA study 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: |   | Seattle |
| State: |   | Washington |
| Zip Code: |   | 98104 |
| 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 WashingtonSeattle, Washington 98104United States***Primary Contact:***Elizabeth Micks, MD, MPH*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**808-203-6500research@fpfellowshiphawaii.org |
| **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 |
|   |
| 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 |
|   |
| Study Arms |

|  |  |  |
| --- | --- | --- |
| **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 |
|   |
| There are no available Sample and Retention Information |

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

Click here to see:

* [Clinical trials for Hemorrhage in Seattle, Washington](http://www.clinicalconnection.com/hemorrhage-clinical-trials-in-seattle-washington)

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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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