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

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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SEARCH FOR CLINICAL TRIALS

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
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
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

Primary Contact:	**Bliss Kaneshiro, MD, MPH** 808-203-6500 research@fpfellowshiphawaii.org
Backup Contact:	**Kate Whitehouse, DO**

Study Dates

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

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

Study Interventions

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

Study Agencies

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

There are no available Study Links

There are no available Study References

Click here to see:

- Clinical trials for Hemorrhage in Honolulu, Hawaii

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

Full Name:

Email Address:

Confirm Email:

Daytime Phone (eg. 555-555-5555):

City:

State:

Zip Code:

Best Time to Call:

☐ Morning ☐ Afternoon ☐ Evening

☐ Please contact me by email instead of calling.

Questions/Comments:

☐ I have read and agree with the Privacy Policy

☐ I have reviewed the eligibility criteria and believe I am eligible for this clinical trial