# Consent

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## Consent

Title: Addition of Buprenorphine to Paracervical Block for Pain Control During Osmotic Dilator Insertion

NCT # NCT04254081

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University of California
Consent to Act as a Research Subject

Addition of Buprenorphine to Paracervical Block Prior to Osmotic Dilator Insertion for Dilation and Evacuation: A Randomized Controlled Trial

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?
Dr. Economou, Dr. Mody, and Dr. Averbach are conducting this research study to find out more about pain control with placement of osmotic dilators prior to a Dilation and Evacuation procedure. You have been asked to participate in this study because you are going to have osmotic dilators placed today. There will be approximately 114 participants enrolled in this study. We are performing this study at UC San Diego Health and at Planned Parenthood of the Pacific Southwest. None of the investigators of this study have any conflicts of interest.

Why is this study being done?
The purpose of this study is to determine if the addition of a medication called buprenorphine to cervical anesthesia (a paracervical block) helps with pain control during and after osmotic dilator insertion. A paracervical block involves placing lidocaine near the cervix to stop pain in the nerve fibers. Buprenorphine is a medication that can be added to nerve blocks in order to (1) decrease pain at the time of the procedure and (2) increase the amount of time that the anesthesia helps to control your pain. Buprenorphine is currently used as an additive to local anesthesia for joint blocks in orthopedic surgery but has not been used in a paracervical block. We want to find out if adding buprenorphine to your paracervical block will decrease discomfort at the time of your osmotic dilator insertion and several hours after insertion.

What will happen to you in this study and which procedures are standard of care and which are experimental?
If you agree to be in this study, the following will happen to you:
1. The risks and benefits of participation will be explained to you and you will be asked to sign this consent form.
2. Before the procedure begins, you will be asked to complete a brief survey and indicate your baseline level of pain on a scale from 0-10.
3. During the procedure, you will receive an injection of a numbing medicine called lidocaine near the cervix to help with pain. This happens for all patients who get dilators placed and is standard of care.
4. The study medication, buprenorphine, is a medication that can be added to the numbing injection. This medication may reduce the amount of pain you feel at the time of your procedure and to may help the numbing injection to last longer. The Food and Drug Administration (FDA) has not approved the use of buprenorphine (the study medication) in a numbing injection. This is called an off label use. Buprenorphine is FDA approved for other things, such as the treatment of chronic pain and the treatment of drug abuse.
5. You will not be told which numbing injection (lidocaine alone or lidocaine plus study medication) you have received. You will be assigned by chance to a study group. Your chance of being assigned to each group is 1 in 2 or 50%. Neither you nor the researcher(s) can choose the group to which you will be assigned.
6. Your clinician will insert the osmotic dilators in the normal way that is standard of care for this procedure. During the procedure, you will be asked to mark your pain level on a scale from 0-10 at several different times. During and after the procedure, you will also be asked about symptoms you may have experienced from the injection.
7. Five minutes after your procedure is complete, you will be asked to assess your pain on the same 0-10 scale. You will also be given a brief survey. Once you feel well enough, you will be discharged from clinic.
8. Afterwards, you can take ibuprofen, acetaminophen, or a stronger narcotic pain medication (if prescribed) as needed for any additional pain.
9. You will receive three text messages after your clinic visit at the following times:
a. 1 hour after your procedure
b. 2 hours after your procedure
c. 6 hours after your procedure
These text messages will have a link to a survey that will ask you to rate your pain, any symptoms you may be experiencing, and what medications you have taken. As part of this study, we ask you to complete each of these surveys. You will need to have access to a cell phone connected to the internet in order to complete these surveys. Because you are receiving text messages which link to the internet, you may be charged standard text messaging and data rates per your cell phone carrier.
10. Immediately before your dilation and evacuation procedure, you will again be asked to assess your pain on a numeric rating scale. You will also be asked other questions about any symptoms you experienced and what pain medications you took overnight.

This will conclude your participation in the study. No further follow-up is needed.

How much time will each study procedure take, what is your total time commitment, and how long will the study last?
The total amount of time for consent, paracervical block placement, insertion of osmotic dilators, in clinic questionnaires, and follow up (including text message) questionnaires will take approximately 45 minutes.

What risks are associated with this study?
Participation in this study may involve some added risks or discomforts. These include the following:

You will be assigned to a study group at random (by chance). Your assignment is based on chance rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. Your assigned study group might also prove to be less effective or have more side effects than the other study groups(s), or other treatments available for your condition.

Side effects of the study medication (buprenorphine) include feeling sleepy, vertigo, dizziness, headache, fatigue, itching, sweating, nausea, constipation, vomiting, temporary elevation of liver enzymes. Rare side effects of the study medication include swelling, bruising or redness at the injection site; low blood pressure; constricted pupils; fainting; or slow breathing.

Placement of the dilators today is the start of your abortion procedure. In the event that you decide to continue the pregnancy after the dilators are placed, we would remove the dilators, but the pregnancy would be considered high risk. Risks to continuing the pregnancy after you had dilators placed include miscarriage, early labor and/or early delivery of the baby, breaking your water early, infection, excessive bleeding, death of the fetus or baby. If you decide to continue the pregnancy, we would refer you to a high-risk pregnancy specialist for the rest of your pregnancy.

If you decide to continue the pregnancy after receiving the study medication, it is unknown if there is any harm to the fetus from the medication. However, we do not have research studies that give us information about the effects of one dose of this medication on a fetus. There may be harm or malformations to the fetus that we cannot predict or do not anticipate.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

There is also a risk of loss of privacy. We will be assigning you a patient study number and will not use your name on any study documents or information. Your personal information will not be disclosed to others. All data will be kept on a secure computer that requires password access only available to the study team members. We will also need to collect your email address in order to send e-gift cards for compensation. These email addresses will also be stored in a secure, password protected database. With these precautions, the risk of loss of privacy is low but still exists.

What are the alternatives to participating in this study?
The alternatives to participation in this study are to not participate. The standard procedure for pain control during osmotic dilator insertion is a paracervical block with 20 milliliters of 1% lidocaine. Participation in this research project is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this institution.

What benefits can be reasonably expected?
There may or may not be any direct benefit to you from these procedures. It is possible that there is a benefit of buprenorphine and you could have less pain during your dilator insertion. The investigators may learn more about pain control during osmotic dilator insertion which may help women having this procedure in the future.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled.

Can you be withdrawn from the study without your consent?
You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Who is paying for this study?
The study is funded by a grant through the Fellowship in Family Planning.

Will you be compensated for participating in this study?
In compensation for your time, you will receive up to $40 in Amazon e-gift cards for participating in this research. You will receive a $20 e-gift card after the osmotic dilation insertion and an additional $20 e-gift card on the morning of your D&E procedure if you complete all follow up questionnaires.

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study. The study medication (buprenorphine) and numbing medication (lidocaine) will be supplied at no cost while you take part in this study. You and/or your health plan/insurance company will need to pay for all of the other costs related to the osmotic dilator placement and dilation and evacuation procedure while in this study, per standard clinical care.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at (858) 246-4777 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. You will be identified only by a unique

identification number and your personal information such as name, address, etc. will not be disclosed to others in order to maintain confidentiality. The data collected from the study will be kept on a secure computer requiring password access, and paper forms will be kept in a locked and secure file in the clinic. Research records may be reviewed by the UCSD Institutional Review Board and FDA.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can you call if you have questions?
Dr. Economou and/or study team members have explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach the family planning study team at 858-329-4464.

You may call the Human Research Protections Program Office at (858) 246-4777 to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent
You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

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Subject's name (printed)

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Subject's signature

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Name of person obtaining consent (printed)

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Signature of person obtaining consent

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