University of California, San Diego
Consent to Act as a Research Subject

# Higher volume paracervical block for pain control in dilation and curettage: a randomized controlled trial

***Who is conducting the study, why have you been asked to participate, how were you selected, and what is the approximate number of participants in the study?***

Dr. Mody and research team at UCSD are conducting a research study in collaboration with Dr. Rible, Dr. Taylor and research team from UCLA to find out more about pain control with dilation and curettage (D&C). You have been asked to participate in this study because you are going to receive a D&C today. There will be approximately 120 participants at all sites.

***Why is this study being done?***

The purpose of this study is to determine if different volumes of liquid in a paracervical block can improve pain control. A paracervical block is placing lidocaine near the cervix to stop pain in the nerve fibers. The higher volume paracervical block contains more saline but the same amount of lidocaine than the lower volume paracervical block. Both paracervical blocks are currently used in practice in this clinic, and lidocaine is FDA approved to provide local anesthesia.

***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 level of baseline pain on a visual analogue scale. You will then receive an injection of Toradol and oral Versed.
3. During the procedure, you will receive a paracervical block, which happens during all D&C procedures. A paracervical block is placing lidocaine near the cervix to stop pain in the nerve fibers. The higher volume paracervical block contains more saline but the same amount of lidocaine than the lower volume paracervical block. Both paracervical blocks are currently used in practice in this clinic, but the lower volume block is used more widely throughout the country. You will not be told which paracervical block 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. Neither you nor the researcher(s) can choose the group to which you will be assigned.
4. Your clinician will perform the D&C in the usual fashion. During the procedure you will be asked to mark your pain level on a visual analogue scale for speculum (the instrument that goes in the vagina to help see the cervix) insertion, paracervical block placement, cervical dilation, and when the uterus is being emptied. At the time of paracervical block placement, you will also be asked about side effects you may have experienced from the injection.

5. At the completion of the procedure, you will be asked to assess your pain on a visual analogue scale at 10 minutes after the procedure and overall pain. You will also be given a brief survey.
6. Afterwards, you can take acetaminophen or ibuprofen as needed for any additional pain.

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?***
After you consent to participate, the total amount of time for pre-medication, D&C procedure, paracervical block placement, and follow up survey will take approximately 1 hour.

***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 to which you are assigned might not be the group you would prefer. Your assigned study group might also prove to be less effective or have more side effects than the other study group, or other treatments available for your condition.

With either paracervical block, moderate discomfort with the injection is a common and expected known side effect. Some other relatively common side effects include dizziness, ringing in the ears, palpitations, tingling around the mouth, and a metallic taste in the mouth. These side effects are mild and usually last for a short duration. A few cases of serious heart problems or death have ever been reported.

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.

***What are the alternatives to participating in this study?***
The alternatives to participation in this study are not to participate. 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. The investigators, however, may learn more about pain control during D&C procedures which may help women receiving D&Cs 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 you may 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 be withdrawn from the study if you do not follow the instructions given you by the study personnel.

***Will you be compensated for participating in this study?***
In compensation for your time, you will receive a $20 Amazon e-gift card for participating in this research. You will receive this gift card by email within 24 hours after you have completed study participation.

***Are there any costs associated with participating in this study?***
There will be no cost to you for participating in this study. The paracervical block 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 D&C 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, email 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 cabinet in the office of the research team. 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 website will not include information that can identify you. At most, the website will include a summary of the research study results. You can search this website at any time.

***Who can you call if you have questions?***
Dr. Mody 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 call the research team at 858-329-4464.

You may call the UCSD 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.

_____ _____

Subject's signature Date

## SUBJECT'S BILL OF RIGHTS

It is important that the purpose and procedures of the research study are fully understood and that consent is offered willingly. A subject in a research study or someone, who is asked to give consent on behalf of another person for such participation, has the right to the following:

1. Be informed of the nature and purpose of the research.

2. Be given an explanation of all procedures to be followed and of any drug or device to be used.

3. Be given a description of any risks or discomforts, which can be reasonably expected to result from this research study.

4. Be given an explanation of any benefits, which can be reasonably expected to the subject as a result of this research study.

5. Be informed of any appropriate alternative procedures, drugs, or devices that may be advantageous and of their relative risks and discomforts.

6. Be informed of any medical treatment, which will be made available to the subject if complications should arise from this research.

7. Be given an opportunity and encouraged to ask any questions concerning the study or the procedures involved in this research.

8. Be made aware that consent to participate in the research may be withdrawn and that participation may be discontinued at any time without affecting continuity or quality of medical care.

9. Be given a copy of the signed and dated written consent form.

10. Not be subjected to any element of force, fraud, deceit, duress, coercion, or any influence in reaching the decision to consent or to not consent to participate in the research.

If you have any further questions or concerns about your child's rights as a research subject, please contact your research doctor or UCSD's Human Research Protections Program at 858-246-HRPP (858-246-4777).