Cover Page

TITLE: Ketamine versus Fentanyl for Surgical Abortions: A Randomized Controlled Noninferiority Trial

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UNIVERSITY OF WASHINGTON CONSENT FORM

Ketamine versus Fentanyl for Surgical Abortions: A Randomized Controlled Noninferiority Trial

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records. A description of this clinical trial will be available on https://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.

KEY INFORMATION ABOUT THIS STUDY

The investigators wish to determine if ketamine is a satisfactory alternative to fentanyl for pain control during first trimester abortions. Your consent is being sought to participate in this research, and your participation is voluntary. If you consent to participate in this research, you will be involved for 2 weeks after your procedure. We will ask you to complete an eligibility form, a preprocedure survey, a postprocedure survey, a followup survey 1 day after your procedure, and a follow up survey 1 week after your procedure. Participating in this study has the potential benefit of receiving a more satisfactory pain medication during your procedure. The risks include breach of confidentiality, or someone finding out about your participation in the study, or potentially receiving a less satisfactory pain medication during your procedure. If you choose not to participate in this study, your anesthetist will determine the safest pain medication to give you, which may be advantageous to you. If either of these medications would be unsafe for you, you will not be enrolled in this study.

PURPOSE OF THE STUDY

Although abortions are one of the most common procedures performed worldwide, many different techniques are used for pain control throughout the world and within the United States. Most clinics use a combination of intravenous (IV) sedation and local anesthesia. Most providers are comfortable using IV fentanyl; however, this is not a good option for everyone. IV ketamine has been widely used for trauma cases in the emergency department and decreases pain in patient with opioid use disorder. Few studies have examined the use of IV ketamine for surgical abortions. The purpose of this study is to examine the satisfaction with pain control when using IV ketamine versus IV fentanyl.

STUDY PROCEDURES

Participation in this study will require a pre-procedure survey, a post-procedure survey, and 2 follow up surveys at home lasting 1-week total. If you choose to participate in this study, before your procedure, you will fill out a survey about yourself and your medical and sexual history. You can refuse to answer any of these questions if they make you uncomfortable. This survey will take approximately 10 minutes and will be given to you while you are waiting for your procedure. You will then be randomly assigned to receive either IV ketamine or IV fentanyl, similar to flipping a coin. Only your anesthetist will know which medication you receive; your provider will not know. If you need additional pain medication during your procedure, the anesthetist will administer additional pain medication and this information will be collected from your medical record to use for the study. After your procedure, you will fill out another survey asking about your experience with the pain medication you received. This survey will take approximately 5 minutes. The next day, you will receive a text message with a link to another survey that will ask you about your mood, pain, satisfaction with the pain medication you received, and use of pain medications. This survey will take approximately 10 minutes. One week after your procedure, you will receive another text message with a link to a final survey that will ask about your mood, pain, constipation, and use of pain medications. This survey will take approximately 10 minutes. You may receive up to 4 additional text messages if you have not responded to the survey within 48 hours. These text messages will be sent through a third party web service and will not contain any identifying information about your abortion or participation in this study.

RISKS, STRESS, OR DISCOMFORT

There is a risk of loss of confidentiality about your participation in the study from receiving text messages about the followup surveys for this study; however, the text messages will not contain any information about you or the procedure. Answering some of the questions in the surveys may make you uncomfortable. You do not have to answer any questions that make you uncomfortable. Survey answers will be stored with your subject ID only and will not be associated with your name. A breach of confidentiality may result in negative psychological effects due to people knowing about your abortion. However, we will ensure confidentiality of any identifying information. By enrolling in our study, there is the potential that you may receive a drug that is unsafe for you. However, we have strict inclusion criteria and eligibility questionnaires that will mitigate this risk. Additionally, the anesthetist who consents you as per routine clinic practice will have the ability to determine if you are ineligible for this study for other reasons and always has the ability to give medications outside of the protocol if necessary for your safety.

RISKS OF MEDICATIONS

The possible risks of receiving IV ketamine include:

- Nausea
- Vomiting
- Dizziness
- Vision changes
- Drowsiness
- Confusion
- Bad dreams

The possible risks of receiving IV fentanyl include:

- Intense happiness or excitement
- Confusion
- Drowsiness
- Nausea
- Vision changes

- Constipation
- Difficulty moving
- Hallucinations
- Addiction
- Losing consciousness
- Low blood pressure
- Difficulty breathing

All participants will receive midazolam per standard clinical care, which may help reduce some of the side effects of the medications. In addition to these risks, there may be unanticipated side effects. If you experience any side effects that endanger your safety, your anesthetist and provider will treat you appropriately. If you experience any of these side effects after you leave the clinic, you should contact Jennifer Chin at 206.221.9074.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Taking part in this study is completely voluntary. It will not affect the care you receive at Cedar River Clinics or the University of Washington in any way. You will receive appropriate anesthesia as determined by your anesthetist. You or you anesthetist can choose either or both medications. You may also leave this study at any time.

BENEFITS OF THE STUDY

By participating in this study, you will help expand the knowledge of IV ketamine for pain control in outpatient surgical abortions in the first trimester. This knowledge will help us take better care of patients who choose to have surgical abortions in clinics and potentially give patients a non-opioid alternative for pain control. You may potentially receive a more satisfactory pain medication by participating in this study, or you may not benefit directly from participating in this study.

SOURCE OF FUNDING

The study team and the University of Washington is receiving financial support from the Society of Family Planning.

CONFIDENTIALITY OF RESEARCH INFORMATION

Data will be confidential. Your study data will be linked to your name via a subject ID number. All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we are mandated reporters and must contact emergency services to ensure your safety and the safety of others. Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm. 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.

Using Your Data in Future Research

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form. You will be compensated for your time and effort to participate in this study. After you complete your first follow up survey at home, you will receive a $25 gift card within 1 week. After you complete your second and final follow up survey at home, you will receive another $25 gift card within 1 week. This will total $50 in gift cards in total. Depending on your cell phone plan, you may incur charges related to the use of text message surveys. If you would prefer not to receive text messages, you may request an emailed survey link instead.

A copy of the consent form will be emailed to you at an email address that you provide. It will be a "PDF" document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn't already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher listed on page 1 of this consent form.

RESEARCH-RELATED INJURY

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call her at the number listed at the top of this form. This number is monitored 24 hours a day. If you are injured as a result of being in this study, necessary medical treatment will be offered at a UW Medicine facility. The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. You may also call collect to the UW Human Subjects Division at 206-221-5940 if you do not otherwise have access to a telephone. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form. We will bill your health insurance for treating problems that result from your surgical abortion or from standard clinical care. If you have no health insurance or your insurance refuses to pay, we will bill you.

SUBJECT'S STATEMENT

This study has been explained to me. I volunteer to take part in this research. I understand that individual research results will not be released to me. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions

about my rights as a research subject, I can call the Human Subjects Division at 206.543.0098 or call collect at 206.221.5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject: _____

Signature of subject: _____

Date: _____

Copies to: Researcher, Subject