CONSENT FORM

Scheduled Prophylactic Antiemetics for Reduction of Emesis with Doxycycline (SPARED) Trial

Principal Investigator: Dr. Sarah Betstadt

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your routine medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you will be taking an antibiotic called doxycycline prior to your scheduled abortion procedure.

This study is being conducted by Dr. Sarah Betstadt, Dr. Amy Harrington, Dr. Olivia Higgins and Dr. Rachel Flink-Bochacki of the University of Rochester's Department of Obstetrics and Gynecology.

Purpose of Study

Doxycycline is an antibiotic that is routinely given to women before an abortion in order to prevent infection. A common side effect of this antibiotic is nausea and vomiting. The purpose of this study is to see if giving an anti-nausea medicine, Zofran (ondansetron) along with the doxycycline will decrease the number of patients who experience nausea and vomiting after taking the doxycycline.

Zofran is approved by the Food and Drug Administration (FDA) to treat nausea and vomiting.

This is a randomized, double-blind study. This means that if you decide to participate, it will be determined by chance (like the flip of a coin) whether you will take ondansetron or a placebo along with the doxycycline. A placebo is like a sugar pill; it has no active drug in it.

Description of Study Procedures

If you decide to take part in this study, you will be asked to:

1. Fill out two questionnaires asking about you, your medical/surgical history, and any symptoms of nausea, vomiting, pain, and anxiety so far in your pregnancy. These two questionnaires will be filled out at your clinic appointment 1-2 days before your procedure, and should take you about 5 minutes to complete.
2. Be randomized to either ondansetron or placebo. You will have a 50/50 chance of taking ondansetron or placebo. Neither you nor the study doctors will know which group you have been assigned to. A member of the study team will give you the study medicine. The night before your abortion, you will take the study medicine about 30 minutes before you take the doxycycline.
3. Fill out a symptom/medication log at home the night before your procedure. In this log you will write down any symptoms of nausea, vomiting, pain, and anxiety you experience from the time you take your study medicine to the time you show up for your procedure. In the log you will also write down what time you took your medications, including the study medicine, doxycycline, misoprostol, and pain medications as needed.
4. Fill out a final questionnaire right before your procedure asking you about your symptoms of nausea, vomiting, pain, and anxiety.
5. Allow us to review and collect some data from your medical record about your procedure.
6. Allow us to perform an additional blood draw of approximately one teaspoon in the operating room before your procedure. This sample will be stored for future testing to measure the amount of doxycycline in your blood. Because the blood is being drawn from an IV that is placed for your procedure, you will not have any additional needle sticks for participating in this research study.

Number of Subjects

Approximately 320 subjects will take part in this study.

Duration of the Study

Your participation in the study will last two or three days, depending on whether you have one or two clinic visits before your procedure.

Risks of Participation
By participating in this study, it is possible that you may have a reaction to either ondansetron or the placebo pill. Possible side effects of ondansetron include diarrhea, headache, fever, lightheadedness, dizziness, drowsiness, constipation, rash, blurred vision and muscle spasm. It is also possible that you may pay more attention to your symptoms of nausea, vomiting, pain and anxiety simply because we are asking you about them.

Some of the questions in the questionnaires may be upsetting or make you feel uncomfortable. You can skip any questions you do not want to answer and you can stop at any time.

Blood draws may cause pain, redness, bruising or infection at the site of the needle stick; these are the same risks as the IV placement that is part of your procedure. Rarely some people faint.

There is also a risk that your confidential information may be exposed. However, we take very strict measures to prevent this (like keeping your personal information in a secure location that cannot be accessed by anyone other than the research team), and the possibility of this happening is extremely low.

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 website at any time.

Benefits of Participation
You may benefit from having less nausea and vomiting from the doxycycline by being in this research study.

Sponsor Support
The University of Rochester is receiving payment from the Mae Stone Goode Foundation for conducting this research study.

Costs
You will not have to pay for the study medicine. The doxycycline and the misoprostol are standard care for your procedure. You and/or your insurance company will be responsible for paying for these medicines as part of your standard care. You are encouraged to discuss your coverage with your insurance provider.

Payments
You will not be paid for participating in this study.

Circumstances for Dismissal
You may be withdrawn from the study if you do not take either the study medicine or the doxycycline.

Compensation for Injury
If you are directly injured by the drug that is being studied, or by the clinical procedures solely required to participate in the study, you may need to pay for treatment of your injuries, but you will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your health insurer or third parties. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes
The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will keep your confidential information in a locked filing cabinet in a secure location where only the research team will have access to it. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study
- Results of medical tests

Who may use and give out information about you?
- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:
- The Department of Health and Human Services
- The University of Rochester
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been

completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Dr. Sarah J. Betstadt at 585-276-5367.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

Storage of Specimens for Future Use

We would like your permission to store your blood sample for an additional future research test. The only test performed on your blood sample will be a measure of serum levels of doxycycline. Your sample will be stored at a secure location at the University of Rochester Medical Center. Only the study personnel will have access to your sample. Your sample will be labeled with a unique study ID number, not with your name or initials.

You can decide if your sample can be saved for future testing. Your decision can be changed at any time by notifying the study personnel. Your decision about your samples will not affect your participation in this study of your medical care at this institution.

Please check the box next to your choice below:

☐ I agree to allow my sample to be kept for future doxycycline testing.

☐ I do not agree to allow my sample to be kept for future doxycycline testing.

Study ID # _____

SIGNATURE/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____
Subject Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date