UNIVERSITY OF WASHINGTON
CONSENT FORM

Aztreonam for the treatment of pharyngeal gonorrhea: A demonstration study

Researchers:

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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.

PURPOSE OF THE STUDY

Gonorrhea is a common sexually transmitted disease that is unique in its ability to develop resistance to antibiotics – that is, the bacteria changes so that it cannot be killed by standard antibiotics. At present there are only two recommended drugs to treat gonorrhea – ceftriaxone (a shot) and azithromycin (pills) – that are used together. However, we are now seeing gonorrhea that cannot be treated with azithromycin, or cefixime a cousin-drug of ceftriaxone. New drugs are urgently needed. Although some new antibiotics are being studied, looking to older drugs is another possibility to quickly identify additional treatments for gonorrhea. This study plans to test a single dose of aztreonam for the treatment of gonorrhea of the throat. Aztreonam is an antibiotic that has been used since 1968, but has not been used routinely for gonorrhea treatment. We are focusing on gonorrhea of the throat because these infections are common, play an important role in the development of antibiotic resistance, and are harder to treat than gonorrhea of the genitals. We plan to enroll 50 people with gonorrhea of the throat in a demonstration study conducted at the Seattle & King County STD Clinic to test whether a 2g shot of aztreonam cures gonorrhea of the throat.

STUDY PROCEDURES

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

- an enrollment visit (today)
- a test of cure (TOC) visit (in 4-7 days)

Each of these study activities are described in more detail below.

Enrollment Visit: At the enrollment visit, you will meet with study personnel for about 1 hour, including the time it takes to review this form. After you have reviewed and signed this form, the formal study procedures will begin.

Intake & Data Entry Form:
The study coordinator or clinician will ask you questions, review your clinic chart and measure your height and weight, and complete a basic data entry form which includes contact information, demographic information (include sex assigned at birth, current gender identity, sexual orientation, race/ethnicity), HIV status, anatomic sites of infection, height, weight, concurrent medications and medical history. Persons of childbearing potential will have a pregnancy test.

Diagnostics and Baseline Clinical Data:
The study clinician will take swabs for culture from all body parts that were or could be positive for gonorrhea. This will include the throat and possibly the rectum, urethra and/or cervix, per routine clinical care. A throat specimen is taken by gently touching a swab to the back part of the throat and moving it up and down, and over the tonsils for 5-10 seconds (like a strep test). Rectal swabs involve inserting a small q-tip like swab in the rectum approximately 3 cm and twirling it around approximately five times. To obtain a urethral swab, the clinician will use a smaller swab and insert it approximately 0.5 – 1 cm into the urethra and twirl 1-2 times. For women cervical specimen collection requires a pelvic exam with speculum. Once the cervix visualized the clinician inserts the swab into the opening approximately 1 cm and spins it about 5 times.

Treatment:
Once all swabs have been taken, the study clinician will give you 2g aztreonam as two4mL shots into your bottom, one in each buttock. S/he will record the time of injection.

Counseling and Follow-up Plan:
The study clinician and/or coordinator will help you set up a follow-up appointment in the next 4-7 days to return to ensure that your infection was cured. S/he will also counsel you about avoiding sexual activity until after your next visit. Sexual activity includes performing oral sex, deep kissing, and oral-anal sex.

Test of Cure Visit (TOC): You will return to the PHSKC STD Clinic to meet with the study clinician 4-7 days (+/- 1 day) after the enrollment visit. This visit should last about 30 minutes. The study coordinator will call you the day prior to the visit as a reminder. At the TOC visit:

Diagnostics:
The study clinician will swab your throat, and any other anatomic sites that were infected at enrollment (e.g. urethra, rectum) again to obtain a culture for gonorrhea. If the culture is positive

for gonorrhea, meaning that the medication did not cure you of the infection, study personnel will call you to return for the standard of care treatment – Ceftriaxone 250mg as a shot plus Azithromycin 1g orally once.

Behavior and Symptom screen:
The study clinician will ask you questions about any symptoms you may have had since your treatment to see how well aztreonem is tolerated. The form will also ask about sexual activity, including kissing, in the time period between treatment and TOC visit.

OTHER STUDY PROCEDURES

Access to Medical Records: As part of this study, we are requesting your permission to access your medical records. We will collect information about when you originally tested for gonorrhea, and other infections, and the results of the cultures conducted as part of this study, including information about antibiotic resistance

RISKS, STRESS, OR DISCOMFORT

There is a risk that someone could find out personal information about you, including your HIV status, which could lead to psychological stress and discomfort. We will do everything possible to diminish this risk by using only a unique study ID on all of your data elements.

As with all drugs, there are potential for allergic reactions and side effects. Documented side effects of aztreonam include decreases in your blood counts, elevations liver function tests, skin rash, diarrhea, nausea, and vomiting; these side effects occur in <2% of cases. We will ask you about possible side effects at your TOC visit, and you can call us if you think you might be experiencing a side effect. A University of Washington medical facility can treat you, but the costs of the treatment may be billed to you or your health insurance just like other medical costs.

If you have any side effects or injury, such as increased stress, from participating in this study, you should call Dr. Lindley Barbee at 206-744-2595 or Dr. Matthew Golden at 206-744-6829.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Choosing to participate or not participate in the study will not affect your care at the Public Health – Seattle & King County STD clinic and/or Harborview Medical Center. If you choose to not participate in this study, we will treat your for your infection as a clinic patient.

BENEFITS OF THE STUDY

One direct benefit of participating in the study is treatment for gonorrhea. Additionally, the knowledge gained from this study will benefit society by helping us determine whether aztreonem is a possible new treatment for gonorrhea.

CONFIDENTIALITY OF RESEARCH INFORMATION

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying

information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
  state or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others

Most of your samples and survey responses will only be labeled with your study ID number. We will store your study data separately from information that identifies you. However, we need to maintain a link between your study ID and your personal information in order to conduct the study. The link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law. All study data will be stored securely on password-protected computers or in locked cabinets in a locked office. Some of the samples you provide (i.e. swabs for culture) are also clinical specimens and will be identified with your name and medical record number (MRN). However, there will be no indication on these specimens that they are part of a research study. We will obtain the results of these tests via the medical record. It will be recorded in the electronic medical record that you were treated as part of a research study.

As gonorrhea is an infection that is required to be reported to public health authorities, please note that you will be contacted by PHSKC disease intervention specialist for an interview, if you have not been contacted already.

Government or university staff sometimes reviews 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.

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. You will be reimbursed for your time with $25 for today's visit and $50 for the TOC visit, or $75 total. This money will be provided in the form of cash at the TOC visit. If you choose to not return for the TOC visit, we will mail you a cash card with $25 on it.

FUNDING SOURCE

The study team and/or the University of Washington is receiving financial support for this research from the National Institutes of Health and a University of Washington Royalty Research Fund grant.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, call Dr. Lindley Barbee at 206-744-2595 or Dr. Matthew Golden at 206.744.6829. If neither of the Investigators are available, please call the 24-hour number listed at the top of this form. For a life-threatening problem, call 911 right away or seek help immediately. Contact the study investigators when the medical emergency is over or as soon as you can.

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. 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. 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. If you have no health insurance or your insurance refuses to pay, we will bill you.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. 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