INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY

Daily Doxycycline 200mg for Early Syphilis

What is this study about?

We are conducting this study to see if doxycycline taken as a single daily dose of 200mg for 14 days is an effective treatment for syphilis. Doxycycline 100mg taken twice a day for 14 days is already used to treat early syphilis. Previous studies suggest that 200mg of doxycycline taken once a day should result in high enough blood levels of doxycycline to treat syphilis. However, once daily doxycycline is not a proven treatment for syphilis.

What will you be asked to do?

If you decide to be in this study, we will ask you additional questions about your medical history and measure your height and weight. You will receive doxycycline to be taken as 200mg daily at your first visit. We will send you follow-up text surveys 7 and 15 days after your visit to see how you are doing with your medications and symptoms. You will have follow-up visits every 3 months for up to 6 months to assess your symptoms, recent sexual history, and obtain blood for syphilis testing, which requires 1 tube of blood. Regardless of whether or not you are in the study, we recommend that you return to the clinic for repeat syphilis testing every 3 months. If your syphilis blood test demonstrates response to treatment at the three-month visit, you will end the study early. The blood test we will do is the standard way doctors assess whether someone is cured of syphilis. If you have symptoms or lab test results that suggest that you have a persistent or new syphilis infection, you will end the study early and be re-treated in the Sexual Health Clinic. Your visits to the clinic will take 30-60 minutes. The study will give you an electronic gift card at the end of each visit to compensate you for your time (called “Tango Cards”).

PROCEDURES	Date
Visit 1 – Day of consent • Go through the consent form with a member of the study team and sign the form if you are interested in being in the study. • Answer questions about your medical history. • Have a blood draw. • OPTIONAL STUDY PORTION: Undergo rectal and throat swabs, which you will collect yourself. We will use these swabs to test for syphilis using a research test. We will not give you the results of this test since it is not a	Day of enrollment

proven test for diagnosing or monitoring syphilis. Persons with a vagina who have vaginal receptive sex swab their vagina *instead* of their rectum. • Receive doxycycline to take for 14 days. • OPTIONAL STUDY PORTION: The study will give you 6 additional sets of throat and rectal (or vaginal) swabs to take home. You will collect these swabs yourself every other day and mail them back to the clinic in a single box. • The study will give you an electronic gift card via email. • Schedule your 3-month follow-up at this visit. • You will receive lab results by MyChart.	
Follow-up text message surveys – 7 and 15 days after starting the study • Text message with a brief survey about symptoms and how you are doing with your medication. • The text message on day 15 will include a reminder to mail in your throat and rectal (or vaginal) swabs, if your are participating in the optional swabs. • If the test results from your original appointment suggest that you do not have syphilis, we will call you to let you know that you cannot continue the study. If your test result is negative for syphilis or does not meet study criteria, you should stop current, study-prescribed doxycycline treatment, and we will direct you to the Sexual Health Clinic instead to get treatment and or follow-up testing as indicated. You will still be compensated for the first visit and any completed and returned (by mail) swabs up to the date of the phone call. • If we do not receive your swabs by 1 month, you will receive a reminder phone call (if you are participating in the swab portion of the study).	Days 7 and 15 after enrollment (approximated to next business day)
Visit 2 – This is an in-person visit with a blood draw. • Questionnaire about symptoms, medications you have taken, and recent sexual activity. • Blood draw • Schedule your next study visit. You will not need more study visits if your blood tests show that your syphilis is cured. We will let you know that you don't need another study visit when we send you your lab test results via MyChart. You should still test for syphilis every 3 months as part of your regular medical care.	Month 3
Visit 3 – This is an in-person visit with a blood draw. • Questionnaire about symptoms, medications you have taken, and recent sexual activity. • Blood draw • We will send you your labs results via MyChart. If your lab results do not yet show that you have been cured of syphilis we will refer you to the Sexual Health Clinic clinical team for your continued monitoring and any future treatment needed.	Month 6

Post-Study – After analysis has been completed, we will notify you by text message of the cure rate in the study with a comparison to cure rate seen among people treated with standard treatments.	Post-study

Why might you want, or not want, to participate?

You may want to take part in the study if you would prefer to take doxycycline pills to treat your syphilis infection rather than a penicillin injection and you would be interested in taking medication once daily, as opposed to twice daily. Your participation will assist in establishing whether taking doxycycline once daily could be an option for the treatment of some patients with syphilis, which some patients may prefer and have an easier time completing.

You may not want to take part in the study because, while data support that taking the medication once daily should provide good drug levels to treat syphilis, taking doxycycline once a day has not been studied and is not a proven treatment for syphilis. Higher doses of doxycycline may have increased chances of side effects, especially stomach upset. Some people may sunburn more easily while taking doxycycline. In rare cases, the FDA has reported doxycycline to be associated with decreased blood levels, kidney damage, headaches, vision problems, and ringing in your ears. Of note, it is difficult to predict who will have a reaction to a medication they have not had before. These side effects are generally expected to stop after discontinuing the drug, and our medical team would evaluate you and offer you alternative treatment. You also may not want to participate in a study that could last up to 6 months. Study participants will be asked to discuss their sexual activity and medical history at each visit, which some people may wish to avoid. Finally, breach of confidentiality is a risk for data in any study, despite efforts to minimize risk, and may be a reason you may not want to participate.

If you choose not to participate in the research, the treatment/care available to you for syphilis may include a shot of penicillin OR taking doxycycline 100mg twice daily for 14 days. The research team will discuss these options with you and provide information about the risks and benefits. Regardless of whether or not you are in the study, we recommend that you test for syphilis every 3 months for at least the next year, as some people need to be followed for more than 6 months to see a response to treatment.

Compensation for participation – The study will compensate you as follows, with payments sent 4-8 weeks after each visit or the submission of swabs:

Study visits (up to 3 visits): $75 per study visit

Study visit bonus: $50 total bonus for completing all required study visits and the two text surveys.

Swabs collected at home: This portion of the study is optional and independently compensated. You will be asked to submit self-collected swabs from your throat and rectum (or vagina) that we will test for syphilis. This will include swabs taken every other day on study days 3, 5, 7, 9, 11, and 13. The study will compensate you $25 for each set of swabs you collect and mail in. If your initial lab results do not qualify for the study, we will call you to let you know that you do not need to send in any additional swabs or attend additional study visits. The study will still compensate you for the swabs you collected and visits you attended.

Swabs bonus for collection all 6 sets: $50 bonus for mailing in all 6 sets of swabs

You may stop participating in the study at any time by emailing fkajonny@uw.edu and golden@uw.edu with the subject "Withdrawal from Doxycycline Study" OR by coming to the clinic and informing our study staff in-person that you no longer want to be in the study.

How will we protect the information you provide?

We will protect your confidentiality by recording any data collected for the study in a secure database (REDCap). Information used in the regular clinical treatment of syphilis will still be present in your medical record, as well as notification that you are participating in this study. The database will protect your data by removing all identifying information from it except your participant identification number (PTID) that will be assigned for the study. The PTID number will be matched to your medical record number in a spreadsheet that is secured in a password-protected file in the Public Health Seattle & King County drive. Only members of the study team will have access to your data, though people from the UW or other agencies may access your information to audit study records. When we publish the results of this study, we will not use your name or otherwise identify you. Because the electronic medical record will contain commentary that you have participated in this study, people outside the research team, such as health insurers, health care providers, and anyone you have authorized to access your records, may be able to find out you participated in this study.

The link between your identifiers and the research data will be destroyed by the research coordinators after the records retention period required by state and/or federal law. **Information collected as part of this research may only be used or distributed for future studies after any identifying information has been removed.**

Other information about this study.

Being in this study is voluntary. This means that you can decline to participate. It also means that if you decide to participate, you can decide to stop being in the study at any time without penalty.

This study received funding from the American Sexually Transmitted Diseases Association.

If you have been injured or otherwise harmed by participating in this study, contact a member of the research team at fkajonny@uw.edu and golden@uw.edu. You will be referred for treatment at the Sexual Health Clinic or Harborview Medical Center, as appropriate. There is no additional financial compensation for study-related injury. The costs of treatment for injury 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. 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 syphilis or from standard clinical care. If you have no health insurance or your insurance refuses to pay, we will bill you.

Significant new findings developed during the research which may relate to willingness to continue participation will be provided to the subject.

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

What can you do if you want more information?

Talk to the study team. We are here to help you understand the study. Please ask us any questions you may have, even about things that are not in this document. It is our responsibility to give you the information you need to make a decision and to give you time to think about whether or not you want to sign up.

Talk to someone else. If you want to talk about the study with someone who is not part of the study team, talk about your rights as a research subject, or to report problems or complaints about the study, contact the UW Human Subjects Division.

Study Team	Matthew Golden, MD, MPH (Investigator)– golden@uw.edu Jakar Delacruz (Research Coordinator)— fkajonny@uw.edu
UW Human Subjects Division	206.543.0098 or hsdinfo@uw.edu

Consent presenter statement

By printing my name on this form, I am attesting that I have provided the subject with information about this study. The participant has been given sufficient time to consider participation and I have answered any questions they had. The participant indicated that they understand the nature of the study, including risks and benefits of participating.

Printed name of study staff obtaining consent	Date

Subject's statement

By signing this consent form, I confirm that the study has been explained to me and I volunteer to participate in the research. I have had a chance to ask questions. If I have questions later about the research or feel I have been harmed by participating in the study, I can contact a member of the research team or the UW Human Subjects Division using the information listed above. I will receive a copy of this consent form. I give permission to the researchers to use my medical records as described in this form.

Printed name of subject	Signature of subject	Date