Point of Care Diagnosis of Vaginal Infections to Ensure Accurate Treatment: (PAT Study)

NCT06438575

August 16, 2024

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Study Title	Point of Care Diagnosis of Vaginal Infections to Ensure Accurate Treatment: (PAT Study)		
Consent Version	3.0 16Aug2024	**Protocol Version**	4.0 09Aug2024
Principal Investigator	Sharon Hillier, PhD		
Researcher's phone #	412-641-4242		
Funding agencies	Cepheid		

*********************************KEY INFORMATION*************************************

Vaginal infections are a common gynecologic issue and may cause significant symptoms and discomfort for women. Point of care (POC) tests are used to diagnose infections in the office, with an advantage of quick diagnosis and treatment. Examples of POC tests are urine pregnancy, rapid strep and COVID-19 tests. This study will enroll women with vaginal complaints and compare diagnosis and treatment based on usual care to diagnosis and treatment using a Food and Drug Administration (FDA) approved POC test for the diagnosis of vaginitis. The study is being done to better understand diagnosis, treatment, and satisfaction using POC tests compared to usual care.

If you are eligible and decide to participate in this study, you will be randomized to one of two study arms:

Arm 1: Your healthcare provider will perform their usual evaluation and tests to make the diagnosis and provide treatment, as needed.

Arm 2: Your provider will be asked to use the results of the POC test being used in the study to make the diagnosis and treatment, as needed.

Regardless of arm, all diagnoses and treatment will be provided through your healthcare provider. All participants will be contacted 2 weeks later to answer a questionnaire. Medical records (related to vaginal complaints; up to 30 days from enrollment) will be reviewed by the study team.

The risks associated with participation include inconvenience and breach of confidentiality.

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INTRODUCTION/REASON FOR STUDY

You are being invited to participate in a research study looking at diagnosis and treatment of vaginal symptoms by usual care vs. a POC test. The POC test being used in the study is the Xpert® Xpress MVP test (MVP), which is a FDA-approved test to accurately diagnose bacterial vaginosis (BV), yeast, and trichomonas within approximately one hour from the time of sample collection. Pregnant and non-pregnant women who are experiencing abnormal vaginal symptoms and are being seen at one of the participating offices/departments may be invited to participate.

RESEARCH ACTIVITIES

Enrollment procedures will take place at UPMC Magee-Womens Hospital in the Clinical Translational Research Center or in one of the participating offices/departments.

If you decide to participate, you will:

- Be provided with instructions and asked to self-collect three Q-tip like vaginal swabs in a private location. One of the swabs will be used to run the MVP POC test. The other two swabs will be used for research purposes only.

- Be randomized to one of two arms (50/50 chance; like flipping a coin):
    - ARM 1: Your healthcare provider will perform their usual evaluation and tests to make the diagnosis and provide treatment, as needed. The MVP test will be run later, and the delayed results will be given to your provider/placed in your medical record as described below.
    - ARM 2: The MVP test will be run right after you collect the swab and the result will be ready in approximately one hour. The results will be made available to your provider/placed in your medical record. Your provider will be asked to use the results of the MVP test to make the diagnosis and treatment, as needed.
- Be asked to complete a brief questionnaire (including demographics, current vaginal symptoms, recent treatment, vaginitis history, etc.), which should take less than 5 minutes to complete.
- See your healthcare provider as scheduled and receive diagnosis and treatment, as needed as described above.

PHONE FOLLOW-UP

- Approximately two weeks after enrollment, you will be contacted by the research team to answer a few questions related to your diagnosis, treatment, current symptoms, and satisfaction with your visit. The phone call should take less than 10 minutes to complete.
- If you were randomized to ARM 1, the results of your MVP test will be made available to your provider/placed in your medical record following your phone follow up. If additional treatment is needed, it would be prescribed by your provider.
- Your active participation will end at this visit.

ELECTRONIC MEDICAL RECORD REVIEW

- Researchers will review and collect information from your medical record from the day of enrollment through approximately 30 days later. Information such as symptoms, testing, diagnosis, treatment, etc. will be collected.

LEFTOVER SPECIMENS

Any vaginal swab specimens that remain in the transport medium after the testing is completed may be shipped to Cepheid at the end of the study and used for additional testing related to Cepheid's diagnostic product development. No human genetic testing will be performed with the samples. The samples sent to Cepheid will be anonymous (stripped of study code) and sent with initial testing results only.

PROTECTION OF CONFIDENTIALITY AND PERSONAL HEALTH INFORMATION

To protect your confidentiality, we will use a number instead of your name on all specimens and data collection forms used for analysis. Electronic data is stored in password protected files located on secure computers. If information from this study is shown publicly or published in a journal, we will not mention your name, or anything else that could identify you.

We will make every attempt to protect the privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records.

The following are examples of who may access study records:

- Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study.

- Cepheid, the study sponsor.
- The U.S. Food and Drug Administration (FDA)
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders made by the investigators for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

Researchers will review and collect information (for instance, diagnosis, testing, treatment, follow-up communication or visits, etc.) from your electronic medical record from the enrollment through approximately 30 days. Information related to your participation in this study (i.e. study description, results) will be placed in your medical record.

Per University of Pittsburgh policy all research records must be maintained for at least 7 years following final reporting or publication of a project. In unusual cases, the investigators may be required to release your identifiable research information in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

Your data and specimens used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

RISKS AND DISCOMFORTS FROM TAKING PART IN THIS STUDY

The risks from participating in this research study are minimal and include the following:
Collection of personal health information : loss of confidentiality and inconvenience from study visits or questionnaires.
Self-collected vaginal swabs: discomfort from collecting vaginal swabs.
Text Messaging: breach of confidentiality and text/data rates may apply

BENEFITS TO TAKING PART IN THIS STUDY

Participation in this study may have no direct benefit. You may appreciate the opportunity to contribute to the body of knowledge about POC testing and women's health. However, there is no guarantee that participants will receive any of these benefits.

VOLUNTARY PARTICIPATION

Your participation in this research study is entirely voluntary. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Your doctor may be involved in this research study. You have no obligation to participate. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh, your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

ALTERNATE CHOICES TO PARTICIPATION
You do not have to take part in this study.

COST
Neither you, nor your insurance provider will be charged for the cost of the procedures performed only for the purposes of this research study. You and/or your insurer will be billed in the usual manner for your standard medical care (care you would receive even if you were not participating in this research study).

STUDY PAYMENT FOR PARTICIPATION
You will receive payment of $20 after completion of enrollment visit and $60 after the completion of the two-week phone call. A parking voucher will be offered if you parked in the UPMC Magee-Womens Hospital parking lot.

Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the Accounting Office. All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099-Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but they would receive only 76% of the expected payment because the IRS requires that 24% of the payment be sent by the institution to the IRS for "backup withholding".

RIGHT TO WITHDRAW
Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. If you withdraw from this study, data that has already been collected may not be removed from the research database. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, please contact the investigator, Dr. Sharon Hillier, and/or research staff at 412-641-4242.

REMOVAL FROM STUDY
Investigators (study doctors) or the Institutional Review Board (a committee at the University of Pittsburgh charged with protecting the safety and rights of people taking part in research studies) can remove you from the research study without your approval. This could happen if you are unable to fulfill the requirements of the study (i.e. you decide you do not want to self-collect swabs or do not attend your scheduled clinic visit).

PROBLEMS OR QUESTIONS
If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

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.
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VOLUNTARY CONSENT FOR PARTICIPANTS
The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be

answered by a qualified member of the research team or by the Principal Investigator listed on the first page. I understand that I may always request that my questions, concerns or complaints be addressed by the Principal Investigator. At any time, I may also contact the Human Subjects Protection Advocate of the Human Research Protection office University of Pittsburgh (1-866-212-2668) to discuss problems, concerns and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. By signing this form, I agree to participate in this research study and provide authorization to use and share my medical records for the purposes described above. A copy of this consent form will be offered to me.

_____
Printed Name of Participant

_____ _____ _____
Participant Signature Date Time (am/pm)

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research to the above individual and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about the study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____
Printed name of Person Obtaining Consent Role in Research Study

_____ _____ _____
Signature of Person Obtaining Consent Date Time (am/pm)