Informed Consent to Participate in Research and Authorization to Collect, Use, and Share your Health Information

Information to Consider Before Taking Part in this Research Study

Title: Effectiveness of phenazopyridine for pain following urodynamics, a randomized control trial

Study # 007227

Overview: You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is being led by Elizabeth Wilkinson who is a fellow at USF College of medicine, department of OBGYN, UROGYN division. This person is called the Principal Investigator. She is being guided in this research by Katie Propst. Other approved research staff may act on behalf of the Principal Investigator.

Study Details: This study is being conducted at USF Urogynecology clinic at STC. The purpose of the study is to determine if taking phenazopyridine (AZO) at the time of urodynamic study testing will decrease pain experienced by patients after undergoing urodynamic testing. Urodynamic testing (UDS) is a procedure that looks at how the lower urinary tract (the bladder, sphincters, and urethra) work to store and release urine. Phenazopyridine (AZO) is an over-the-counter medication that is commonly used for its pain-relieving effects when patients have urinary tract infections. The research will be carried out at the time of scheduled urodynamic testing. Some patients will receive oral treatment with a dose of phenazopyridine at the time of their UDS (experimental arm) and the other patients will not. UDS will be performed per the normal standard of care process. The treatment you get will be chosen by chance (randomization), like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given either treatment. All patients in the study will be contacted 4 to 6 hours afterward via telephone for follow up.

Subjects: You are being asked to take part because your physician has determined you need urodynamic testing as part of your care management. We want to find out if this treatment will help patients who undergo urodynamic testing.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start.

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. There is no cost to participate. You will not be compensated for your participation. The most common and most serious risks that may be related to taking part in this research include minor discoloration of urine to a more serious anaphylactic reaction to the phenazopyridine.

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Why are you being asked to take part?

This study includes the use of a drug for the treatment of pain. Phenazopyridine is approved by the Food and Drug Administration (FDA) for the treatment of pain, burning and discomfort caused by infection or irritation of the urinary tract. It is being used as part of this research study to find out if taking phenazopyridine will be effective pain management for patients undergoing urodynamic testing.

Study Procedures: What will happen during this study?

You will arrive to the urodynamic testing appointment as scheduled. Prior to beginning of the testing, you will sign the consent form to participate in the research study. You will complete the pre-procedural visual analog scale (VAS) for anxiety and anticipated pain. If you have been randomized into the experimental arm you will be provided a single dose of 199 mg phenazopyridine (AZO) to take by mouth with a sip of water at the beginning of urodynamic testing. Urodynamic testing will proceed as it would if you were not participating in the study (standard of care). At the completion of urodynamic testing, you will receive a VAS for pain and anxiety to be filled out again. Prior to leaving your appointment, you will be handed an additional sheet of paper containing a VAS scale for pain and anxiety and question regarding UDS testing. You will be receiving a phone call from a member of the research team 4 to 6 hours after you leave to remind you to complete the scale and question and return via mail with a pre-stamped envelope. This will complete your participation in the research study, and you do not need to complete any further action.

Total Number of Subjects

About 66 individuals will take part in this study at USF.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study.
You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time.

You can decide after signing this informed consent document that you no longer want to take part in this study for any reason at any time. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

- We will tell you how to stop safely.
- If you decide to stop, you can continue getting care from your regular doctor.

Please note, even if you want to stay in the study, there may be reasons we will need to withdraw you from the study. You may be taken out of this study if we find out it is not safe for you to stay in the study or if you are not coming for the study visits when scheduled. We will let you know the reason for withdrawing you from this study.

Benefits

We are unsure if you will receive any benefits by taking part in this research study.

Risks or Discomfort

The following risks may occur from the use of phenazopyridine (AZO)

Phenazopyridine is known to turn your urine/tears the color orange.

Rare:

- blue or blue-purple color of skin
- fever and confusion
- shortness of breath, tightness in chest, wheezing, or troubled breathing
- skin rash
- sudden decrease in the amount of urine
- swelling of face, fingers, feet, and/or lower legs
- unusual tiredness or weakness
- weight gain
- yellow eyes or skin

Less common or rare:

- dizziness
- headache
- indigestion
- itching of the skin
- stomach cramps or pain

Compensation

You will receive no payment or other compensation for taking part in this study.

Costs

It will not cost you anything to take part in the study. If randomized to experimental arm, the phenazopyridine medication will be provided by the study. You and/or your insurance company will not be billed for the medication.

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further.

Compensation for Research Related Injuries

If you are experiencing an emergency, call 911. If you believe you have been harmed as a result of participating in this study, you should call Elizabeth Wilkinson at 813-259-8500 as soon as possible. The University of South Florida has not set aside money to pay for illness or injury that may result from your participation in research.

The cost of illness or injury that may result from your participation in research will be billed to your insurance company or to you in the event you do not have health insurance.

Before you agree to take part in this study, you may want to find out whether your insurance will cover injuries that result from taking part in research. You may be responsible for any deductible, co-insurance, or co-payments that result from such care. If you are injured, the University of South Florida has also not set aside money for lost wages, discomfort, or disability you may experience as a result of a research-related injury. By signing this form, I acknowledge the University of South Florida will not pay for the costs of medical care and treatment, or any associated costs such as lost wages, due to injury arising from participation in this study. You do not give up your legal rights by signing this form. In addition to contacting the study investigator, you should also contact the USF Institutional Review Board (IRB) at 813-974-5638 or RSCH-IRB@usf.edu if you believe you have been injured as a result of taking part in this study.

Conflict of Interest Statement

There are no conflicts of interest to disclose.

Privacy and Confidentiality

We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may need to see your study records. These individuals include:

- The research team, including the Principal Investigator, study coordinator, physicians apart of the research team, clinical medical assistants and all other research staff.

- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- Any agency of the federal, state, or local government that regulates this research. This includes the Department of Health and Human Services (DHHS), the Office for Human Research Protection (OHRP), and the Food and Drug Administration (FDA).
- The USF Institutional Review Board (IRB) and its related staff who have oversight responsibilities for this study, and staff in USF Research Integrity and Compliance.

Your information collected as part of the research, even if identifiers are removed, will NOT be used or distributed for future research studies.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website 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 if new information becomes available about the study?

During this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in this study. We will notify you as soon as possible if such information becomes available.

We may learn things about you from the study activities that could be important to your health or to your treatment. If this happens, this information will be provided to you. If randomized into the experimental arm and a drug reaction happens, patient will be informed, and reaction documented in the patients' medical record in MyChart. All patients will have access to urodynamic testing reports in their medical record based on standard operating procedures of USF clinics. You may need to meet with professionals with expertise to help you learn more about your research results. The stdy team/study will not cover the costs of any follow-up consultations or actions.

You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call Dr. Elizabeth Wilkinson at 813-259-8500. If you have questions about your rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting the University of South Florida to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than USF who are also involved in the research and listed below.

In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research:

- The medical staff that takes care of you and those who are part of this research study;
- Each research site for this study including University of South Florida Morsani College of Medicine clinic
- Any laboratories, pharmacies, or others who are part of the approved plan for this study;
- The USF Institutional Review Board (IRB) their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research;
- Data Safety Monitoring Boards or others who monitor the data and safety of the study;

Anyone listed above may use consultants in this research study and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, USF may collect, use, and share the following information

- Your research record
- Data regarding your urodynamic testing results, and medical history

You can refuse to sign this form. If you do not sign this form, you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke your authorization at any time by sending a letter clearly stating that you wish

to withdraw your authorization to use your health information in the research. If you revoke your permission:

- You will no longer be a subject in this research study;
- We will stop collecting new information about you;
- We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
- Staff may need to follow-up with you if there is a medical reason to do so.

To revoke your authorization, please write to:

Principal Investigator: Elizabeth Wilkinson, MD
For IRB Study # 007227
University of South Florida
Department of Obstetrics and Gynecology
South Tampa Center for Advanced Healthcare
2 Tampa General Circle, 6th floor
Tampa FL, 33606

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies.

Consent to Take Part in Research and Authorization for the Collection, Use and Disclosure of Health Information

I freely give my consent to take part in this study and authorize that my health information as agreed above, be collected/disclosed in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

_____ _____

Signature of Person Taking Part in Study Date

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Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent and Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

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Signature of Person Obtaining Informed Consent Date

_____

Printed Name of Person Obtaining Informed Consent