Official Title: Nitrofurantoin Administration for the Prevention of Short-Term Catheter Associated Urinary Tract Infection After Pelvic Surgery (NAUTICA): A Randomized Controlled Trial
IRB-Approved Date: 7/11/2018
NCT03287089

CAROLINAS HEALTHCARE SYSTEM
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title:	**Carolinas HealthCare System-Department of OB/GYN / Nitrofurantoin Administration for the Prevention of Short-Term Catheter Associated Urinary Tract Infection After Pelvic Surgery (NAUTICA): A Randomized Controlled Trial**
Protocol Number:	**08-17-03**
Principal Investigator: (Study Doctor)	**Dina A. Bastawros, M.D.**
Telephone:	[redacted] **(24 Hours)** [redacted] **(24 Hours)**
Address:	**Carolinas HealthCare System** [redacted] **Carolinas HealthCare System** [redacted]

You will be given a signed and dated copy of the full Informed Consent Form.

WHAT ARE SOME GENERAL THINGS YOU SHOULD KNOW ABOUT RESEARCH STUDIES?

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty or loss of benefits to you.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the Carolinas Health Care System and its affiliates.

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If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a signed and dated copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

WHAT IS THE PURPOSE OF THIS STUDY?

Urinary tract infections (UTI) are the most common complication after pelvic organ prolapse or urinary incontinence surgery. It can affect up to 35% of women undergoing these surgeries.

Sometimes, the risk of a UTI is increased with the use of a catheter. A catheter is placed after surgery if you have difficulty emptying your bladder. Difficulty emptying your bladder can happen in up to 50% of women undergoing pelvic organ prolapse or incontinence surgery. Because of this, all of our patients have bladder testing after surgery to make sure they are able to void (urinate) after surgery. If they are not able to void, they must go home with a catheter.

Complications of UTIs can include kidney infection and bloodstream infection. Therefore, it is important to reduce the risk of a UTI after surgery. However, using antibiotics too often can cause development of resistant organisms, making it difficult to treat bacterial infections.

There has been research done to evaluate many different types of antibiotics to prevent UTIs in women that need to have a catheter for a few days following surgery. There is also some research that shows that no antibiotics may be needed in these women. Although some of these studies show that antibiotics can help reduce the number of UTIs, the type of antibiotic and treatment duration is not well defined.

The purpose of this research study is to learn if an antibiotic is effective in reducing the risk of UTI after the short-term catheter is removed following surgery.

You are being asked to be in the study because you plan to undergo surgery for pelvic organ prolapse and/or urinary incontinence.

HOW LONG WILL YOUR PART IN THE STUDY LAST?

Your participation in this study will include the office visit in which you are enrolled, your operation, and your postoperative recovery time. As part of your routine care, you will have a bladder test done in the hospital after your surgery.

If you are unable to successfully void, you will be discharged home with a catheter. You will return to the office in 1-7 days for catheter removal. At that time, if you have consented to

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participate in the study, you will be given 5 day supply of either an antibiotic or placebo medication ("study drug") that you are to take two times a day until finished. You will need to keep a medication log of all the times you have taken the study drug.

You will follow up at your previously scheduled 2 and 6-week follow-up appointments. Your involvement in the study will then be complete.

ARE THERE ANY REASONS YOU SHOULD NOT BE IN THIS STUDY?

You should not be in this study if you have had a UTI before surgery, have kidney problems, are pregnant, or have an allergy to the antibiotic (nitrofurantoin).

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

There will be approximately 180 people in this research study.

VOLUNTARY PARTICIPATION

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in our practice for UTI. You may change your mind later and stop participating even if you agreed earlier.

The study doctors will receive no financial benefit in any form by asking you to participate in this study.

WHAT WILL HAPPEN IF YOU TAKE PART IN THE STUDY?

- Before surgery you will be screened to ensure you do not have a UTI.
- Following surgery, you may have a catheter in place. When it is time, if you have a catheter in place, you will have a bladder study. The study nurses will fill your bladder with fluid, remove the catheter, and give you 60 minutes to urinate. The study nurses will then measure how much urine you voided, and how much urine is left behind in your bladder.
    - If you urinated more than 200mL (less than 1 cup) and have less than 1/3 of the total urine volume left in your bladder, you have successfully voided and your involvement in the study is complete.
    - You will be asked to complete a questionnaire assessing how forceful you feel your stream of urine was.
    - If you are unable to urinate more than 200mL, and you have more than 1/3 of the total urine volume left in your bladder, then you have not successfully voided. A Foley catheter will be replaced and you will go home with this catheter.

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- You will return to the office in 1-7 days for a repeat bladder study, similar to what was done in the hospital. If you successfully urinate, you will be randomized, or assigned by chance, like flipping a coin, to a study group.
    - All women in study Group A will be given a 5-day supply of nitrofurantoin, which is an antibiotic approved by the U.S. Food and Drug Administration (FDA) to treat UTI. This will be taken two times a day until all pills are gone.
    - All women in study Group B will be given a 5-day supply of a placebo. This will be taken two times a day until all pills are gone.
    - Both the antibiotic (nitrofurantoin) and placebo pills will look exactly the same. A placebo looks like real medicine but it does not have any active ingredients. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the placebo. For the research to be good, it is important that you do not know whether you have been given the real medicine or the placebo. This is one of the best ways we have for knowing what the medicine we are testing does.
    - It is important that neither you nor we know which of the two drugs you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.
- The first pill will be taken in the office. You will complete a medication log outlining every time you took a pill. You will need to bring this medication log with you at your 2-week postoperative appointment.
- You will return for a 6-week postoperative appointment. At that time, we will follow up with you to identify if you had any incidences of a UTI in the first 30 days following surgery. If you develop a UTI during the study, you will be treated with an antibiotic.
- The study doctor and the team of Urogynecology physicians will be responsible for your health care throughout all study procedures. They will be looking after you and the other subjects very carefully during the study. If we are concerned about what the study drug is doing, we will find out which study drug you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research please talk to the researchers.

INFORMATION ON NITROFURANTOIN

The antibiotic that we are testing is called ***nitrofurantoin***. It is an antibiotic that is commonly prescribed to treat UTIs, as well as prevent them. We now want to test this antibiotic to see if it can prevent UTIs in women who had a catheter after surgery.

Side effects of nitrofurantoin include:

- diarrhea
- nausea
- vomiting
- vaginal discharge

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- upset stomach
- gas

Some subjects in the research will not be given the antibiotic, which we are testing. Instead, they will be given a placebo, which does not have any active ingredients in it. There is no risk associated with taking placebo, although it is possible that your risk of getting a UTI may be higher (that is what this study is trying to find out).

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS STUDY?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS INVOLVED FROM BEING IN THIS STUDY?

There may be uncommon or previously unknown risks. You should report any problems to the researcher. The risks associated with this study are minimal. Potential risks you may experience may be a small risk of developing a UTI from catheterization. However, this is the standard treatment for women who are unable to void after surgery. You should let your study doctor know if you have signs or symptoms of a UTI (for example, burning or pain on urination or bloody or cloudy urine).

Another risk may be drug intolerance (for example, if you take nitrofurantoin, your body could become resistant to its ability to kill UTI-causing bacteria).

If you are a woman who is pregnant or is planning to get pregnant, you should not be in the study, as nitrofurantoin could cause harm to a developing fetus.

IF YOU CHOOSE NOT TO BE IN THE STUDY, WHAT OTHER TREATMENT OPTIONS DO YOU HAVE?

Whether or not you are in this study, you will receive standard surgical care for your condition. This may or may not include antibiotics to prevent UTI – this depends on your surgeon's standard practices. You would get treated for a UTI if you develop one whether or not you are in this study. The study doctor will discuss the risks and benefits of other treatments with you.

WHAT IF WE LEARN ABOUT NEW FINDINGS OR INFORMATION DURING THE STUDY?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

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CONFIDENTIALITY

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

HOW WILL YOUR PRIVACY BE PROTECTED?

No subject will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, Carolinas Health Care System will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the medical center, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

- If you choose to enroll in this study by signing this consent form, you will be assigned a study number that will be used on all examination forms and questionnaires; no other identifying information will be used on these forms.
- Your signed consent forms will be maintained in two places: one copy will be kept in your medical record and a second copy will be kept in a locked file cabinet in a locked office. The copy in your medical record will allow the study doctors caring for you to know what study procedures you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study.
- Only the study personnel: the study doctor, Faculty Advisors, and the Study Coordinator and affiliated study personnel will have access to an electronic file linking your name to your study number. This file will be maintained on a password protected computer system and terminal and will be destroyed when the entire study is complete.

WILL YOU RECEIVE ANYTHING FOR BEING IN THIS STUDY?

You will not receive anything for taking party in this study.

WILL IT COST YOU ANYTHING TO BE IN THIS STUDY?

It will not cost you anything in addition to what you will be billed for your routine medical care to be in this study. All tests, visits or procedures other than what is done for this study will be related to medical care that is part of the usual care for your condition and would be suggested even if you decided not to be in the research study.

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Here are some examples of standard medical care that may be performed within this study: office urinalysis, urine culture, and a voiding trial.

WHAT WILL HAPPEN IF YOU ARE INJURED BY THIS RESEARCH?

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. Despite all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The Carolinas Health Care System has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

WHAT IF YOU WANT TO STOP BEFORE YOUR PART IN THE STUDY IS COMPLETE?

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Carolinas HealthCare System. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Carolinas HealthCare System.

You can withdraw from this study at any time, without penalty. The study doctors also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.

AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor and the study investigator to collect, process and pass on to the sponsor organizations any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

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- the study doctor and study staff,
- the study sponsor and/or its associated companies, Carolinas HealthCare System,
- regulatory or other governmental authorities of the United States and other countries,
- other persons authorized by the study sponsor,
- Carolinas HealthCare System employees,
- other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study,
- monitor your treatment with the study drug,
- compare and pool study treatment results with those of other subjects in clinical studies,
- support the development of the study drug,
- support the licensing application for regulatory approval of the study drug in the world
- support the marketing, distribution, sale and use of the study drug anywhere in the world.

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Carolinas HealthCare System.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed; it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study investigator and sponsor will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely.

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If you wish to revoke authorization to use your personal information, you will notify the study doctor in writing at the address and telephone number listed on the first page of this form. Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

WHOM TO CONACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser: Pro00022622.

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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STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent

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