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Official Title: Evaluating the Effect of Tamsulosin on Postoperative Urinary Retention in Women Undergoing Same Day Hospital Discharge Following Pelvic Reconstructive Surgery: A Randomized Trial

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Evaluating the effect of Tamsulosin on Postoperative Urinary Retention in Women undergoing Same Day Hospital Discharge Following Pelvic Reconstructive Surgery: A Randomized Trial

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Informed Consent Form to Participate in Research

SUMMARY
You are invited to participate in a research study. The purpose of this research is to help determine if starting tamsulosin (commercially known as Flomax) 5 days prior to surgery will help decrease your chances of going home with a bladder catheter the same day of your surgery, and continuation for 5 more days after surgery to avoid retention of urine in near future. You are invited to be in this study because you have decided to undergo a vaginal approach for treating your pelvic organ prolapse. Your participation in this research will involve your first 2 postoperative visits and will last 6 weeks.

Participation in this study will involve you receiving 0.4 mg (standard dose) of tamsulosin or a placebo pill once a day for 10 days (4 days before the surgery, 1 pill on the day of surgery before the procedure, and 5 pills after surgery). You will take the pill at the same time, early morning between 07:00 and 09:00). The placebo pill is an inactive substance (usually sugar) prepared to look as similar to the active product investigated in a study as possible. You will be chosen to receive either type of pill at random based on a computer-generated algorithm. You may know which pill you have received when your individual study has concluded which will be at your 6-week visit. Tamsulosin medication is FDA approved, however use in women is not approved by the FDA.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Your other choice is to not receive either the tamsulosin or the placebo and still undergo your proposed surgical plan. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.
The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Majid Mirzazadeh, MD, the principle investigator of this study and Amr El Haraki, MD, co-investigator. If you have questions, suggestions, or concerns

regarding this study or you want to withdraw from the study their contact information is:
[redacted]
If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION
You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have pelvic organ prolapse and will be undergoing vaginal corrective surgery for this. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?
The purpose of this research study is to help determine if preoperative tamsulosin will decrease your chances of going home with a bladder catheter on the same day of your surgery, and potentially thereafter. We will also assess whether or not you have a postoperative urinary tract infection, urinary retention as well as your overall improvement of urinary tract symptoms on a questionnaire and if you needed prolonged catheterization.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
88 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
At your first visit, you will have a baseline post void residual (the amount of urine left in your bladder after you have emptied it in the restroom) measured by a bladder scanner (a portable ultrasound machine that will determine how much urine is left in your bladder); fill out a form to determine if you are eligible to participate in the study) and receive one medication bottle which will contain either the tamsulosin or placebo. You will be instructed to start taking the pill 4 days prior to day of surgery, start filling out the provided form to indicate date and time of investigation medication taken.
After surgery, we will start an active voiding trial on the day of surgery. This involves filling your bladder up prior to removing the catheter and checking to see how well you empty your bladder. This is standard for all our patients whether or not they are part of the study.
At your first postoperative visit one week from surgery, we will measure your post void residual again, obtain a urinalysis to look for infection and have you

fill out a questionnaire. You will also return your medication bottle at this visit with the completed form indicating 10 days and time of dosage. We will review the form with you to verify the information. If you have a visit before one week, you will be requested to take the bottle back with you to complete 10 days of dosing and return the bottle by next visit (6 week time).
At your second postoperative visit six weeks from surgery, we will measure your post void residual again and obtain another urinalysis.

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in any group.
You will either fall in a group of study patients who receive tamsulosin or a group of study patients who receive placebo pills. You will not be informed the group you are in to avoid any effect on your selections of your postoperative questionnaire

HOW LONG WILL I BE IN THE STUDY?
You will be in the study for about 6 weeks.
You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. Currently, there are no serious consequences for withdrawing early from the study.

WHAT ARE THE RISKS OF THE STUDY?
This study trial may or may not benefit to you. Tamsulosin medication may potentially be helpful in increasing your chances at passing your voiding trial (Voiding trial is a trial to pass urine) after surgery; therefore, there is a risk that you may be assigned to a group that does not perform as well as its comparison.
Of note, tamsulosin has not FDA-approved use in women. At the present time, we do not use alternatives to tamsulosin as this is a new indication for usage.
All research studies involve some risks. Risks of this study to be aware of comprise of the side-effects of tamsulosin which include, but are not limited to orthostatic hypotension which is a drop in blood pressure when standing or sitting up, dizziness, postoperative atrial fibrillation, abdominal pain, asthenia- (weakness), constipation, dry mouth, headache, runny nose, diarrhea , fainting, nausea , insomnia – difficulty falling sleep, back pain, runny eyes , floppy iris syndrome (a rare condition that occurs during cataract surgery, which causes a poor pupillary dilation).Though rare, this drug
can cause severe skin reactions, including a serious condition called Stevens-Johnson syndrome.
These skin reactions can cause raised welts, facial swelling, fever, and

trouble breathing You may or may not receive benefit by participating in this study.
The risks associated with this study are the risks associated with the drug in addition to any inherent surgical risks for the surgery you will be receiving which do not change with this study. These risks are the same if you chose to participate in this study or not.
In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Reproductive Risks and other Issues to Participating in Research
Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), Depo Provera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions. Pregnant women are excluded from participation in this study. Because some methods of birth control are not 100% reliable, a pregnancy test is required at least 10 days from your last normal menstrual period, if you are a sexually active woman of childbearing potential.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
You may or may not receive benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?
You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options: To undergo your scheduled surgery without use of preoperative medication that can potentially increase your chances of succeeding your voiding trial.

WHAT ARE THE COSTS?

All study costs will be paid for by the study. Costs for your regular medical care, which are not related to this study will be your own responsibility. You will not be charged for the investigational medication (10 pills).

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified. Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?
You will receive no payment or other compensation for taking part in this study. The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?
This study is being sponsored by Wake Forest Baptist Health Department of Urology. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?
Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other

compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services. You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Drs. Majid Mirzazadeh (principle investigator) or Amr El Haraki (research study co-investigator) at [redacted], 24 hours a day and 7 days a week.

WHAT ABOUT MY HEALTH INFORMATION?
In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** postvoid residual measurement, urinalysis, urinary symptom questionnaires
If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations. We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products. Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries. Your health information may be disclosed if required by law. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.
If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others.
If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.
Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Drs. Majid Mirzazadeh or Amr El Haraki that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:
Dr. Majid Mirzazadeh and Dr. Amr El Haraki
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.
Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Amr El Haraki, MD or Majid Mirzazadeh, MD at [redacted] (24 hours a day, 7 days a week). The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted] You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

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Subject Name (Printed):_____
Subject Signature: _____
Date: _____Time:_____ am pm
Person Obtaining Consent (Printed):_____
Signature of person obtaining consent:_____
Date:_____ Time:_____ am pm

WFU School of Medicine
Institutional Review Board
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