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Atrium Health Department of OB / GYN
Division of Female Pelvic Medicine and Reconstructive Surgery

AT HOME EARLY VS. DELAYED CATHETER REMOVAL FOLLOWING FAILED POSTOPERATIVE VOIDING TRIAL IN PELVIC RECONSTRUCTIVE SURGERY: A RANDOMIZED TRIAL (AHEAD CARE)

Informed Consent Form to Participate in Research
Megan Tarr, MD, MS Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is determine the potential benefits for early at home urinary catheter removal. You are invited to be in this study because you are having outpatient pelvic reconstructive surgery. Your participation in this research will involve no additional scheduled visits aside from your usual postoperative care and may require an hour of your time.

Participation in this study will involve the medical risks related to urinary retention and indwelling transurethral catheters. All research studies involve some risks. A risk to this study that you should be aware of is the potential for urinary retention requiring an additional clinic visit to the office, post anesthesia care unit (PACU) or Emergency room. You may or may not benefit from participation in this study.

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. Some other choices may include continuing with your usual preoperative care. 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. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [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 Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies help scientist learn new information that may help other people in the future. You are being asked to be in this study because you will be undergoing pelvic reconstructive surgery. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. 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 see whether patients who self-remove their urinary catheter that empties their bladder 1 day after surgery have a similar rate of needing to get the catheter replaced into their bladder (due to inability to urinate) compared to patients who self-remove their urinary catheter 3 days after surgery.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

104 women at one research site will take part in this study. In order to identify the 104 women needed, we may need to screen as many as 500 people because some women will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

Women scheduled to undergo pelvic reconstructive surgery will be identified and screened against inclusion and exclusion criteria. If potential subjects meet the requirements for the study, they will be eligible to be invited to participate. Women will be consented for study enrollment by physicians, fellow physicians, nurse practitioners, physician's assistants, and/or a research nurse, and/or study team member prior to surgery at either their pre-operative visit or the morning of surgery.

In the post anesthesia care unit after surgery, you will have a voiding trial to assess your ability to urinate prior to discharge from the hospital. This is the standard of care and occurs routinely after pelvic reconstructive surgery even in women who are not part of the study. A voiding trial begins with your bladder being filled with sterile water in the operating room while you are asleep under anesthesia. After surgery, upon your arrival to the post anesthesia care unit, you will be given 60 minutes to attempt to empty your bladder. If you can empty at least half of the fluid filled in your bladder, then your voiding trial is considered successful ("a pass"). If you are unable to empty your bladder of at least half of the fluid, then this is considered a "failure" to void. Women who fail to empty their bladders as noted above are sent home with a temporary catheter to drain their bladder. If you agree to be part of this study, you will be randomized to

remove your catheter either on the third day after surgery (which is our current standard of care) or the first day after surgery (which is our intervention group). For women who do not have difficulty with urination after surgery and pass their voiding trials, their involvement in the study is complete.

Randomization means that you are put into a group by chance. It is like flipping a coin. Randomization will occur after a failed postoperative voiding trial. You will be given specific instructions on when and how to remove your urinary catheter at home. On the day of your catheter removal, the study staff will contact you to assess if you are urinating well (emptying your bladder well) on your own and administer the study questionnaires. You will resume your usual postoperative care. We will continue to monitor you for 30 days postoperatively via your medical record.

If you take part in this study, there are no additional scheduled procedures performed for research or investigational purposes. You will be required to answer questionnaires via email and/or phone call on the day of your urinary catheter removal to assess for urinary retention (trouble with urination/emptying your bladder).

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about *1 month.* 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. There are no known serious consequences of sudden withdrawal from the study. You will be required to continue your usual postoperative care as outlined by your physician team.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures we are studying include:

Uncommon risks	The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be significantly more than in daily life postoperatively from pelvic reconstructive surgery or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Confidentiality and privacy	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.

There also may be other risks 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 to your health.

A Data Safety Monitor, an independent expert, will be reviewing the data from this research throughout the study to identify possible safety issues to participants and to provide advice and recommendations on possible changes to the research study for the protection of participants.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other women in the future. The benefits of participating in this study may be as good as standard treatment you could receive without being in the study but with the potential for fewer side effects, it may be of benefit to subjects who undergo similar surgical procedures. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study. You should talk to the researchers about all the choices you have. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, including any study products or procedures related directly to the study, 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.

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 or permitted by law, or necessary to protect the safety of yourself or others.

Your 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.

I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WILL YOU BE PAID FOR PARTICIPATING?

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

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. 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. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

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 Dr. Megan Tarr at [redacted].

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**:**

Age, race/ethnicity, Body Mass Index (BMI), post-menopausal status (yes/no), current vaginal hormone replacement therapy use (HRT) (yes/no), current smoking status (yes/no), if sexually active (yes/no)

Surgery data includes: surgeon, concurrent surgeries performed, if vaginal packing placed (yes/no), total surgical duration (minutes, as timed by incision to final closure stitch), total estimated blood loss (EBL), any surgical complications/adverse events. Post operative voiding trial and urinary retention, study 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 the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps 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 Atrium Health Facilities; 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.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. 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, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

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 Dr. Megan Tarr or Dr. Ryan Darvish 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. Megan Tarr
[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. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities 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. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

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. At most, the website will include a summary of the results. You can search this Web site at any time.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this study.

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, Dr. Ryan Darvish, or principal investigator, Dr. Megan Tarr, at [redacted].

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.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date: _____ Time:_____ am pm