Official Title: Randomized Trial of Retropubic Versus Single-incision Mid-Urethral Sling (Altis) for Concomitant Management of Stress Urinary Incontinence During Native Tissue Vaginal Repair
NCT03520114
IRB-Approved Date: 3/16/22

Wake Forest®
School of Medicine

Department of Urology

Randomized trial of Retropubic versus Single-incision Mid-Urethral Sling (Altis™) for Concomitant Management of Stress urinary incontinence during Native Tissue Vaginal Repair

Informed Consent Form to Participate in Research
Catherine Matthews, M.D., Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to compare two different types of slings that are used to treat stress urinary incontinence. You are invited to be in this study because you have shown that you have stress urinary incontinence when your vaginal bulge is returned to its normal position and you have already decided to have surgery to place a sling that will help support your urethra or the tube that carries urine from the bladder to the outside of the body. Your participation in this research will involve study questionnaires and questions at 6 of your regular care visits and last about 12 months.

Participation in this study will involve randomization (like flipping a coin) into two different groups receiving two different types of slings—either a retropubic sling that goes all the way behind your pubic bone and exits through 2 small incisions in the skin or a single-incision mid-urethral sling that attaches on the sides of the pubic bone. This sling does NOT exit all the way through the skin. However, in order to make sure that neither you, or the study nurses know what type of sling was placed, women randomized to the single-incision sling will have 2 tiny skin incisions made in the same location as women randomized to the retropubic sling. These incisions are typically very small and are not painful. Both slings are currently FDA approved devices used for this type of surgery. The study will also include questions about your health and medical history and your current health.

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 not participating and getting your surgery without being in the study. 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 Catherine Matthews, M.D. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: Catherine A. Matthews, M.D. [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 Coordinator at Wake Forest Baptist Health at 3[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 stress urinary incontinence, and you have decided to have surgery for your stress urinary incontinence. 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 compare two different types of FDA approved slings used for the surgery you are about to have.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 280 people at 7 research sites will take part in this study, including approximately 90 people at this research site.

WHAT IS INVOLVED IN THE STUDY?

This study is comparing two types of slings commonly used in patients with stress urinary incontinence. The study doctor believes that neither type is inferior to the other, and this study is being conducted to prove this theory. You will be randomized into one or the other two groups of people receiving either a retropubic sling or a single-incision mid-urethral sling. 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 either group. Neither you, nor your doctor, will be able to change this choice as long as you remain in the study.

The two types of slings used in this study can be described as follows:

The retropubic sling is a u-shaped hammock-like sling of woven mesh that sits under the urethra (the tube that carries urine from your bladder to the outside of your body). It acts like a seatbelt to catch the urethra when you cough or sneeze. The sling is about 8 inches long and ½ inch wide. It is introduced through a 1-inch vaginal incision, and passes behind the pubic bone to exit through 2 tiny incisions on the skin above the pubic bone. This sling has been studied in women for up to 20 years.

The single-incision mid-urethral sling is a shorter sling—about 3 inches long and ½ inches wide. It is made up of the same type of woven mesh material and also sits under the urethra and acts like a seatbelt to catch the urethra when you cough or sneeze. It attaches into a muscle in the pelvis using a small permanent attachment instead of passing all the way behind the pubic bone. This sling has only been studied in women up to 2 years,. If you are randomized to this sling, you will have the same tiny skin incisions made above the pubic bone to make it look "the same" on the outside as the retropubic sling.

If you take part in this study, you will have 6 research visits at the same time as your regular care visits for the surgery. You will also have one phone call visit purely for research.

If you decide to take part in this study, you will give consent by signing this form after you feel satisfied with answers to any questions you may have about the study. You will answer questions about your health and medical history. You will answer questionnaires. The study team will collect information from either the regular care pelvic exam you receive at this visit or recently prior to this visit.

Before your surgery you will be randomized into one of the study groups using one of the two types of slings. And the surgeon will use the sling during your surgery.

The day you are discharged from the hospital, we'll record whether you have had any significant changes to your health and whether you are successfully able to void .

About two weeks after your surgery you will have another regular care follow up visit. At that visit your voiding function will be assessed with a bladder scan and reviewed by the investigator. And you will also be asked about any changes in your health.

About six weeks after your surgery at your regular care follow up visit, you will be given some questionnaires about your health. You will also be asked about any changes in your health. You will have a regular care pelvic exam (specifically a POP-Q exam that measures where your pelvic organs are and if they have moved from their original positions). The study team will collect information from that exam for the study. This exam does not require any specimens and no specimens are collected for the study. The doctor would be performing this exam whether you were in the study or not in the study.

About six months after your surgery someone from the study team will call you to ask you about any changes in your health.

About a year after your surgery at your regular care follow up visit, you will be given some questionnaires about your health and quality of life. You will also be asked about any changes in your health. You will have a regular care pelvic exam (POP-Q) from which the study team will collect information for the study to compare to your previous exams.

Your doctor may ask you to have visits outside the regular care visits here, but these are the only visits that will include research procedures.

If you take part in this study, you will have the following tests and procedures:
Randomization to either a group with a retropubic or a single-incision mid-urethral sling
Questionnaires about your health, quality of life, and pain level
Questions about your health and medical history

How Long Will I Be in the Study?

You will be in the study for about a year. 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.

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. The risks related to these slings would be risks whether you are participating in the study or not participating in the study. Risks and side effects related to the slings used in this study include:

Bleeding
Bladder Injury (Cystotomy or Bladder Trocar Perforation)
Vaginal Wall Perforation
Urethral Injury
Bowel Injury
Nerve Injury
Intestinal Injury
Infection (UTI, Vaginal, Pelvic Abscess)
Bowel Obstruction
Venous Thromboembolism
Mesh Exposure
Leg Pain or Difficulty Ambulating
Fistula
Urinary Retention
Hematoma
Bladder Outlet Obstruction
Urgency “de novo”
Stress or Urgency Incontinence (New or Worsening)
Recurrent POP
Other Urogynecologic Complications: _____

It’s also possible the sling will not help your urinary incontinence and it may even make it worse.

This study is comparing two approved methods for treating your condition. You will be randomly assigned to one of the two groups. It is possible that one treatment group may have a better response than the other. Therefore there is a risk that you may be assigned to a group that does not perform as well as its comparison.

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.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

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), DepoProvera, 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. The surgeon will give you a pregnancy test prior to your surgery if you are of childbearing potential.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct 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 can choose not to participate. Some alternative care options to the bladder sling are the following:

Absorbent products like incontinence pads—they are non-invasive and collect the urine after you accidentally lose urine during a cough or sneeze. There is a risk if you use the absorbent products too long without changing them there may be an unpleasant odor or bacteria may develop

Behavioral therapy such as modifying the amount you drink during certain times during the day—this is also non-invasive. But you may become thirsty or not hydrate enough.

Physical therapy: Pelvic floor muscle exercises can be very effective for the treatment of stress urinary leakage. But they may not be easy to remember to perform, and if you don't do them, they can't help.

Estrogen therapy—some doctors believe estrogen therapy can help with stress urinary

incontinence and some believe it does not. You would need to discuss this option with your medical doctor to determine his/her recommendation. Some side effects of estrogen therapy in women who have stress incontinence can be an increase in your stress urinary incontinence.

Vaginal pessary: Doctors sometimes suggest the use of a vaginal pessary or device that is inserted into the vagina that physically supports the urethra. It has to be taken out and cleaned and reinserted regularly. It can help to keep you from leaking urine when you do things that normally cause you to leak such as coughing or sneezing. Some women experience side effects from pessary use, such as vaginal irritation, foul-smelling discharge, and urinary tract infections.

WHAT ARE THE COSTS?

All study costs and 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. The surgery you are planning and the follow up care visits are considered part of your regular care and the study will not pay for the surgery or the visits. You or your insurance company will be billed for the sling and the surgical procedure to insert the sling.

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 be paid $125 if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be compensated $25 for the visit where you are consented into the study, and $100 if you complete the 1 year post op visit. These are the only two study visits for which you will receive compensation. No other compensation will be given for study participation.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Foundation for Female Health Awareness. 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 Management, at [redacted].

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 Catherine A. Matthews, M.D. at [redacted] (24 hours a day).

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**:** previous pelvic surgeries, significant health problems, demographic information, previous treatments for your incontinence, previous recent pelvic exam information (specifically a measurement of your pelvic floor called a POP-Q), POP-Q information from your follow up care visits within a year of your upcoming surgery. Also, if applicable, pregnancy test results.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may 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; 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.

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.

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. This authorization does not expire, and 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 can tell Dr. Matthews 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:

Catherine A. Matthews
[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 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.

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 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.

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, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped.

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, Catherine A. Matthews, M.D. 24hours a day 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.

PERSONAL PHYSICIAN PERMISSION AND SIGNATURES

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

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