IRB Review
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Informed Consent Form

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Title of Research Study: Mito-LUTS: A Pilot Study of the Effect of MitoQ on Lower Urinary Tract Symptoms in Older Women with Metabolic Syndrome.

Funding Source:

National Institute of Health / National Institute of Aging's Claude D. Pepper Older Americans Independence Center & UConn Health (P30 AG067988) **and** The Urology Care Foundation and American Urological Association New England Section Wyland F. Leadbetter, MD Award (Research Scholar Award)

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Name of Research Participant:

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is voluntary. You can say yes or not. If you say yes now, you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision.

This is a study to test whether a supplement (the study drug, MitoQ) can help improve bladder symptoms that are often experienced by many older women or women who have the metabolic syndrome. These symptoms include urgency (a sudden feeling you want to urinate), frequency (having to go often to the bathroom to urinate), nocturia (waking up often at night to urinate) and incontinence (unintentionally urinating).

The study drug MitoQ used in the study is not approved by the U.S. Food and Drug Administration (FDA) for the uses being tested in this study. The uses in this study are considered "investigational." However, the FDA has authorized the use of MitoQ in this research study. Therefore, MitoQ is considered to be experimental for the purpose of this study and its procedures.

This study uses a placebo. A placebo looks exactly like the study drug, but it contains no active ingredient. We use placebos in research studies to learn if the effects seen in research participants are truly from the study drug.

If you are eligible to participate, you will be randomized (by chance, like flipping a coin) to receive either MitoQ supplement or placebo. Neither you nor the study team will know what you are taking, however the pharmacist will know which drug you are assigned to and taking.

Study participation involves blood and urine testing, many questionnaires about your bladder symptoms, measuring your weight, blood pressure, blood sugar, waist circumference, testing your mobility, testing your cognition, doing electrocardiograms, asking about your medical history and medication you take, and keeping voiding diaries. Participation also grants the PI and study coordinator permission to access your medical records at UConn Health to review your medical history to determine your eligibility for the study.

Participation will involve taking 2 study pills daily 30 minutes before breakfast for 4 months, 4 visits to UConn Health Center on Aging clinical research and several phone calls. Each visit will range in length from 2-3 hours and phone calls will be about 5-10 minutes long.

The risks of this study are mainly related to MitoQ supplement, electrocardiogram (ECG), blood draws and mobility assessments. MitoQ could cause a change to the heart's electricity, which is called ventricular arrhythmia due to delay of ventricular repolarization (prolonged QT segment on the ECG). The QTc segment tells us how long it takes for the heart's electrical system to get ready for the next beat. QTc prolongation could lead to life-threatening arrhythmia, however we will check everyone's heart with a special test called an "ECG" to make sure they are safe to participate in the study. We will do this test regularly during the study to monitor for your safety. In previous studies, we have not seen these types of risks / problems with participants' hearts but will monitor it throughout participation to ensure participants are not at increased risk. The study drug has, in rare instances, given some people an upset stomach, with feelings of nausea or vomiting. Blood draws, which are done by trained research staff, have little risk. Some of the mobility assessments may make you feel like you will lose your balance or fall. These risks and others are described in more detail later in this form.

There is no direct medical benefit to subjects from participation in this study. There is also the possibility that no benefit will come from this study. Others may benefit in the future from the knowledge we gain from this research about new types of drugs we can use to improve the quality of life of women who have bothersome bladder symptoms associated with aging or metabolic syndrome.

A more detailed description of this research follows.

Purpose of this Research

This is a pilot phase of a research study to examine if a supplement, MitoQ, can improve symptoms of bladder disease that often occur with aging and in people who have metabolic syndrome. The purpose of this pilot phase is to determine whether MitoQ has an effect on bladder function prior to performing a larger trial. We also want to get information about how feasible and acceptable this study design is to our participants.

The purpose of this research is to find new ways we can improve bladder symptoms (including urgency, frequency, nocturia, and incontinence) that can result in people due to different underlying medical conditions or unhealthy aging. We also wish to find out about molecules present in blood and urine that can tell us about how serious each person's bladder symptoms are, whether they may benefit from a certain drug and how their body is responding to a drug. We will

do this by studying the relationship between molecules we will measure in your blood and urine and the answers you provide on bladder questionnaires.

Voluntary Participation

You are invited to participate in this study because you are a woman aged 50 or older, have been diagnosed with or fulfill criteria for metabolic syndrome and reported having urgency for at least the past 3 months. Participation is voluntary. Before making a decision about whether to participate in this research study, please read this consent form carefully and discuss any questions you have with the researcher. You may also want to talk with family members, your primary care physician (your doctor), or a friend before making a decision.

You can choose not to participate. If you choose to participate in this study, you can change your mind later and stop participating. If you decide not to participate or you withdraw from the study after starting participation, your decision will not affect present or future medical care you receive at UConn Health. There will be no penalty or loss of benefits of which you are otherwise entitled.

Number of Other People Who Will Participate

We estimate that 50 people will participate in this study at UConn Health.

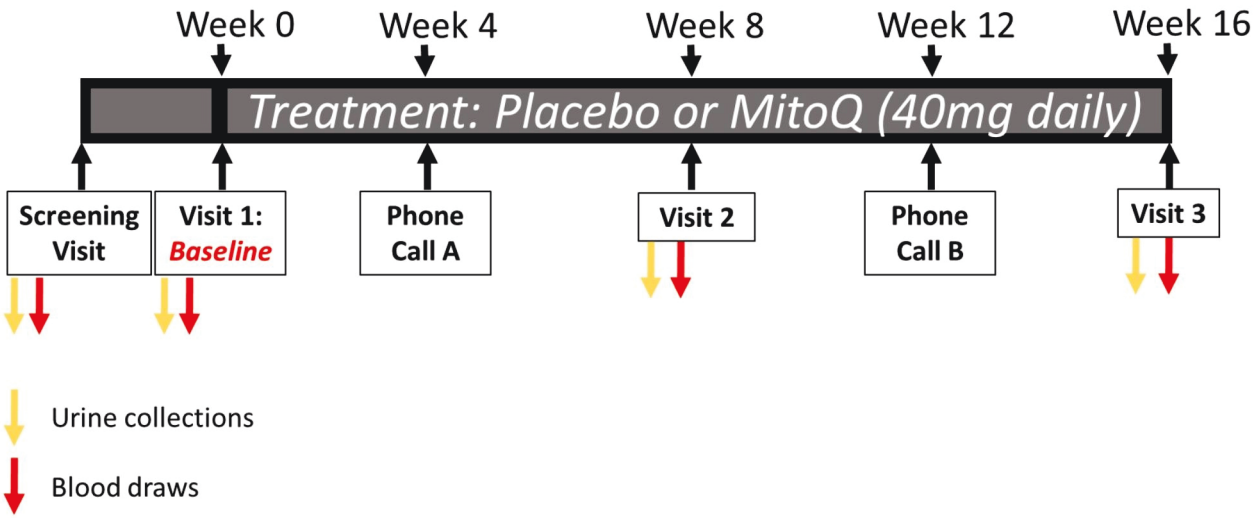
Randomization Process

This study features both experimental and control groups. The experimental group will receive the study drug, whereas the control group will receive similar looking pills that do not contain the study drug. Everything else in the study will be the same for the two groups. Your assignment into either experimental or control group (Placebo) will be done randomly by a computer. Neither you, the research staff nor the PI will know which group you belong to until the end of the study when all the data has been collected and analyzed. You can think of it as a coin flip in which you have a 2 out of 3 chance of being in the experimental or the placebo (control) group. This randomization is very important to our study because it is the only way we can know for sure that any improvement in bladder symptoms is due to the study drug and not because your body thinks you are getting better because you are taking a drug. This can happen in people and is called a placebo effect. One third of study participants will end up in the placebo group whereas two thirds will receive the study drug. This means that you have a 2 out of 3 chance of being in the study drug group and a 1 in 3 chance of being in the control (placebo) group.

Length of Participation

Participation will consist of 4 study visits to the UConn Center on Aging (screening visit and visits 1-3) lasting about 12 hours in total, and several phone calls (two 5-minute calls per week for the first 3 weeks, then 1 5-minute call every other week and two calls lasting 10 minutes each at weeks 4 and 12). The total time you will be asked to take the study drug is 16 weeks (about 4 months). If you qualify for the study after the first telephone call (30 minutes) and the in-person screening visit (~2.5hours), you will be invited to return within 4 weeks for the first visit (Visit 1, 1hours), where you will undergo some tests and receive the capsules. You will then return 8 weeks after starting the study drug (Visit 2, 1.5 hours) and again 16 weeks after starting the study drug (Visit

3, 2.5 hours). We will call you twice a week for the first 3 weeks, then twice a month to check up on you and ask you some questions. There will be a longer call at 4 weeks and one at 12 weeks (10 minutes) where we will also administer some bladder function questionnaires by phone. There may be more calls to check up on you and follow up if needed. Total participation from Screening visit to study completion (Visit 3) can be up to 22 weeks.



Study Visit Details

Screening Visit

This visit will last about 2.5 hours. A more detailed check of inclusion/exclusion criteria will take place at this visit to determine your final eligibility status for this study. If you are found not to fulfill any of the eligibility criteria, you will be excluded from participation in the study.

- You will be asked to fast overnight prior to your visit (don't eat or drink anything besides water after midnight before your visit).
- We will review this informed consent form with you in detail and answer any questions you may have. If you agree to participate and sign the informed consent, the screening visit will continue.
- You will fill out a questionnaire about study acceptability and adherence.
- We will ask you questions about yourself, your medical history and medications you are taking.
- A finger prick to collect a drop of blood for measuring your fasting blood sugar (glucose) will be done.
- We will ask you to provide two urine samples, one at the beginning of the visit and another at the end, to check for any active urinary tract infections and for measuring molecules related to aging and bladder symptoms in the urine.
- A fasting blood sample will be collected to check your blood count, blood chemistry, liver enzymes, kidney function, and metabolic syndrome/diabetes status and for measuring molecules related to aging and bladder symptoms in the blood. About 2 tablespoons of blood will be taken. We will provide you with a light breakfast/snack after the blood draw.
- If you have had a menstrual period within the last 12 months, we will have you take a urine pregnancy test to ensure you are not pregnant.

- We will measure your blood pressure, weight, height, and waist circumference to confirm your metabolic syndrome status and eligibility for the study. We will also measure your heart rate, temperature and blood oxygenation.
- We will test your cognition using a questionnaire to determine your eligibility for the study.
- You will undergo an electrocardiogram (ECG) test to measure your heart's electricity.
- You will fill out questionnaires about your bladder function and symptoms.
- You will complete short physical performance tests. These are simple tests such as balance testing, getting up from a seat, walking a short distance, and squeezing a hand grip meter.
- You will be instructed on how to perform the 24-hour urine collection, the first morning urine collection and the 3-day voiding diary. You may opt out of the 24 hour urine collection without affecting your study participation.
- You will receive $25 for completing this visit.

Visit 1 Baseline

If, based on your answers and results from tests done at the screening visit and results from the blood tests we did on blood we collected during that screening visit, you fulfill the screening criteria and choose to participate in the study, you will be asked to return to the Center on Aging for a Baseline visit (Visit 1). It will last about 1 hour.

- You will be asked to fast overnight prior to your visit (don't eat or drink anything besides water after midnight before your visit).
- Unless you opted out, you will bring in your 24-hour urine sample collection, your first morning urine sample and your 3-day baseline voiding diary. We will review your 3-day voiding diary together.
- We will measure your blood pressure, weight, height, and waist circumference to confirm your metabolic syndrome status. We will also measure your heart rate, temperature and blood oxygenation.
- You will fill out detailed questionnaires on your health and physical activity.
- A finger prick to collect a drop of blood for measuring your fasting blood sugar (glucose) will be done.
- A blood sample will be collected (about 1.5 tablespoons) and you will be provided a light breakfast.
- We will ask you to provide two urine samples, one at the beginning of the visit and another at the end. We will ask you questions to make sure your medical history and medications are correct and up to date.
- You will fill out several detailed questionnaires about your bladder function and symptoms.
- You will be randomized (like a flip of a coin) to receive a supply of either MitoQ pills or placebo pills (a pill that contains no active drug). The capsules will look identical and you will not be told which medication you will receive. You will be instructed to take pills daily starting the next morning and will continue to take this medication daily throughout the duration of the study.
- We will review instructions on how to perform the 24-hour urine collection, the first morning urine collection and the 3-day voiding diary.

- You will receive $50 for completing this visit.

Phone Call A

We will call you 4 weeks (about 1 month) after you first start taking the study drug to ask about any adverse events or issues you are having with the study drug, administer questionnaires about your bladder symptoms, ask about adherence and any changes in your health or medications you are taking. This call will last about 10 minutes.

Visit 2

Approximately two months after you begin taking the study drug, you will be invited to return to the Center on Aging at UConn Health for Visit 2. It will last about 1.5 hours.

- You will be asked to fast overnight prior to your visit (don't eat or drink anything besides water after midnight before your visit).
- Unless you opted out, you will bring in your 24-hour urine sample collection, your first morning urine sample and your 3-day voiding diary. We will review your 3-day voiding diary together.
- We will measure your blood pressure, weight, height, and waist circumference. We will also measure your heart rate, temperature and blood oxygenation.
- A finger prick to collect a drop of blood for measuring your fasting blood sugar (glucose) will be done.
- We will ask you to provide two urine samples, one at the beginning of the visit and another at the end. A blood sample will be collected (about 2 tablespoons) and you will be provided a light breakfast/snack.
- We will ask you questions to make sure your medical history and medications are correct and up to date.
- You will undergo an electrocardiogram (ECG) test.
- You will fill out several detailed questionnaires about your bladder function and symptoms.
- You will turn in old medication and receive new medication.
- We will review instructions on how to perform the 24-hour urine collection, the first morning urine collection and the 3-day voiding diary.
- You will receive $75 for completing this visit.

Phone Call B

We will call you 12 weeks (about 3 months) after you first start taking the study drug to ask about any adverse events or issues you are having with the study drug, administer questionnaires about your bladder symptoms, ask about adherence and any changes in your health or medications you are taking. This call will last about 10 minutes.

Visit 3

Approximately four months after you begin taking the study drug, you will be invited to return to the Center on Aging at UConn Health for Visit 3. It will last about 2.5 hours.

- You will be asked to fast overnight prior to your visit (don't eat or drink anything besides water after midnight before your visit).

- Unless you opted out, you will bring in your 24-hour urine sample collection, your first morning urine sample and your 3-day voiding diary. We will review your 3-day voiding diary together.
- We will test your cognition using a questionnaire.
- We will measure your blood pressure, weight, height, and waist circumference. We will also measure your heart rate, temperature and blood oxygenation.
- A finger prick to collect a drop of blood for measuring your fasting blood sugar (glucose) will be done.
- We will ask you to provide two urine samples, one at the beginning of the visit and another at the end. A blood sample will be collected (about 2 tablespoons) and you will be provided a light breakfast/snack.
- We will ask you questions to make sure your medical history and medications are correct and up to date.
- You will undergo an electrocardiogram (ECG) test.
- You will fill out detailed questionnaires on your health and physical activity.
- You will complete short physical performance tests. These are simple tests such as balance testing, getting up from a seat, walking a short distance, and squeezing a hand grip meter
- You will fill out several detailed questionnaires about your bladder function and symptoms.
- You will fill out a questionnaire about study acceptability and adherence.
- You will fill out study feedback form
- You will turn in remaining study medication.
- You will receive $100 for completing this visit.

Other Calls:
During the first three weeks of participation, the study staff will call you twice a week beginning on the first day you take your study drug to find out if you are taking the study drug as directed and to find out how you are tolerating the study drug. Beginning at Week 4 and throughout the rest of the study, we will call you about every 1-2 weeks to ensure you are taking the study drug, ask about adverse events and report on any other changes in your health/medications, and remind you about upcoming visits and samples/diaries to collect and bring for those visits (5 minutes).

Procedures and Risks

Participation in this research involves several aspects as follows:

MitoQ Dietary Supplement and Placebo: If you are eligible to participate, you will be randomized (by chance, like flipping a coin) to receive either MitoQ supplement or placebo. You are twice as likely to get the study active supplement than the placebo. Neither you nor the study team will know what you are taking, however the pharmacist will know which drug you are assigned to and taking. The pills will look the same and neither the study staff nor you will know which drug was chosen for you. However, this information can be obtained if there is a medical reason that comes up. MitoQ is not FDA approved and is considered an experimental drug for the purpose of this study. You will be

asked to take 2 capsules of the study drug you are given (either MitoQ or placebo) every day for 4 months (1 capsule per day for the first week, then 2 capsules per day for the remaining time). By signing the consent, you are indicating that you are willing to be placed in either group. This is not standard clinical care, however, MitoQ is an over-the-counter supplement that doesn't require a prescription.

Risks: Remembering to take the study drug daily for 4 months can feel burdensome.

Headaches, nausea, vomiting, mild upset stomach may occur when using the study drug. Clinical phase 1 and 2 studies reported 1% adverse events (2 adverse events in 200 participants). MitoQ is not a pharmaceutical. Pharmaceuticals are substances that have gone through the drug approval process, whereas MitoQ is classified as a dietary supplement. There are no known interactions with medications.

If the QT interval on the ECG increases over 500 ms or increases by 50ms or more from the QT interval we measured before you started taking the study drug, you will be asked to stop taking the study drug and discontinue the study protocol. The study physician may also refer you to your physician.

Safeguards: You will start out by taking only 1 capsule per day for the first week, then increasing to two capsules each day thereafter. Study staff will ask you about these potential side effects throughout the study. At any time during the study, if you experience severe gastrointestinal symptoms such as vomiting and/or diarrhea for 3 days in a row, we ask you to immediately stop taking the study medication and call us. If you feel mild symptoms such as headaches, nausea or upset stomach that are not very bothersome to you but last for 5 days in a row, please stop taking the study medication and call us. We will discuss your symptoms with the study doctor and you may be withdrawn from the study if needed for your safety.

It is best to take the study drug 30 minutes to 1 hour before breakfast or another meal. The two capsules should be taken at the same time (but you don't need to swallow them together). However, you may take the study drug with food and water if you have headaches, nausea, and mild upset stomach after using the study drug. You should let the research team know if you experience any side effects or concerns while taking this study drug. We will exclude anyone from participating who has a QTc interval on the ECG over 460 ms. If the heart's electrical activity increases over 500 ms or increases by 50ms or more than before you started taking the study drug, you will undergo a clinical evaluation by the study physician and will be discontinued from the study. The study physician may recommend seeking follow up care with a primary care physician.

- **ECG Assessment**: A 12-lead ECG will be applied to measure the QT interval for safety assessments throughout the study. Application of the ECG will consist of cleaning the skin surface with an alcohol swab, using a skin-friendly low-irritative gel to allow for proper transmission of the signals, and then sticking the electrodes to the skin surface.

Risks: There are minimal discomfort and skin irritation with ECG electrode application and removal.

Safeguards: ECG leads will be removed carefully to prevent skin irritation. You will be instructed to inform the researcher when discomfort or skin irritation occurs. Your skin irritation induced by the electrode will be closely monitored.

- **Survey/Questionnaire administration:** The study staff will ask you to answer several questions in the form of surveys and questionnaires about your health, medical history, bladder symptoms, and other questions about you and the study.

  Risks: You may feel uncomfortable or bored answering some of the questions. There are no physical risks associated with any of the surveys.

  Safeguards: You may always choose not to answer a question that makes you feel uncomfortable. You can always take a short break from answering questions if you need to.

- **Urine Collection:** You will be asked to provide several different types of urine samples (24-hour, first morning, spot sample). There are no physical risks to urine collection.

  Risks: 24-hour urine collections can be tedious and require you to be thinking about your bathroom trips all day, making sure you have all the items needed for collecting your urine in your bathroom, and storing urine in your refrigerator for a day may not be pleasant (3 days total over the 4-month study). First morning urine requires you to setup containers the night before and remember to collect your first morning void before drinking or eating anything. Urinating in a cup can be messy or feel uncomfortable.

  Safeguards: For 24-hour urine collections, you will urinate in a urine collection container placed under the toilet seat. For spot samples, you may also choose to use that urine collection device if you are not comfortable urinating directly into the cup.

- **Fasting Blood Draw:** You will be asked to fast overnight prior to your visit (don't eat or drink anything besides water after midnight before your visit). While in a fasted state blood will be drawn from a vein in your arm or hand by a needle stick. Blood will be drawn from a vein in your arm by a needle stick at each study visit. The amount drawn will be about 1.5-2.5 tablespoons, depending on the visit. You will also have your finger pricked to get a drop of blood to measure your fasting blood sugar at each visit.

  Risks**:** There will most likely be some mild discomfort from the needle stick. Occasionally a bruise will develop at the puncture site and some people may experience dizziness when the blood is drawn. There is a remote possibility of infection at the puncture site. Finger prick for blood glucometer can be painful and pain can last for a few minutes. There is a remote possibility of infection at the puncture site.

Safeguards**:** The area where the needle is to be inserted will be wiped with a disinfectant before the needle is inserted. Only sterile needles will be used. The puncture site will be covered with a bandage. Fingers will be wiped with a disinfectant before finger prick. You will be provided with a small breakfast/snack after your blood is drawn.

- **Voiding Diaries:** You will be asked to keep a record of your fluid intake (what you drink, how much you drink and when you drink it) and urination (what time you urinated, how much you urinated and how much urgency you felt when you went to urinate) for 3 days (back to back or separate days in the week before your study visits). You will do this a total of 3 times (9 days total) during the 4-month study. This bladder diary is similar to one that your physician may have asked you to complete to accurately assess your urinary symptoms as part of routine clinical care

  Risks: Voiding diaries can be tedious and require you to be thinking about and recording your bathroom trips and everything you drink all day and measuring your urine and writing everything down. You may get bored or frustrated.

  Safeguards: You can choose any 3 days where it is convenient for you to do this in the 1-week period before your scheduled visit.

- **Metabolic Syndrome Assessment:** In addition to sugar, fat and cholesterol blood tests, we will measure your blood pressure, height, weight and waist circumference to confirm and track your metabolic syndrome status. We will also measure your other vitals (temperature, heart rate, blood oxygenation).

  Risks: There are no physical risks associated with these measurements. You may feel embarrassed by your weight or waist measurements.

  Safeguards: These measurements will be done privately and your data is protected.

- **Physical Performance/Mobility Testing:** You will be asked to complete simple tests of physical performance, which include balance testing, getting up from the sitting position, walking a short distance, and squeezing a hand grip meter.

  Risks: There is a small chance you could fall, hurt a muscle, overexert yourself, or otherwise become injured during physical performance testing.

  Safeguards: These tests have been used safely in many research studies in the past and we do not anticipate injuries to occur. Trained staff will administer these tests and will watch out for your general safety, especially during balance testing, to prevent any risk of falls. Careful instructions will be given for each test and you can choose to not complete certain portions if you do not feel it is safe for you to do so. You can perform these tasks at a speed of your choosing. Trained staff will conduct all assessments, monitor your status and stay within arms' reach and if you report chest pain, chest tightness, shortness of breath,

lightheadedness, or other issues the testing will be stopped. You may always choose not to do a mobility test and you may stop participating at any time.

- **Other Consideration of Physical or Psychological Risks:** Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

- **Risk to Privacy from Sharing Samples and Data:** We receive money from the National Institutes of Health (NIH) to do this study. NIH requires that we have a plan in place to share information we gain in this study. We anticipate publishing the findings of this research and publishers often require that we have a plan in place to share the information we collect during this study. To promote faster discovery of more effective ways to prevent, diagnose and treat disease, we may also share samples and information (data) for use in other studies.

  Your information will only be shared in an anonymous way. Sharing research data helps to translate research results into knowledge, products, and procedures that improve human health. If you consent to share your anonymized information, you may withdraw your permission later without any penalty or loss of benefit. The information will be withdrawn from the database. However, if the information has already been shared with other researchers that information will not be able to be deleted.

  Your individual data and health information will be anonymized and put into a controlled-access database. Only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. The information may be used for future research. Your data and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database will agree not to attempt to identify you.

  Risks**:** Data and samples from this study may be shared with other researchers for other research projects and in controlled scientific databases.

  Safeguards**:** All samples generated in this study will not be identified by your name or other personal identifiers, but rather will be given a unique study identification code. Thus, samples shared with other research institutions will not contain information that could identify you. Additionally, before any data is placed in online scientific databases, the data will be given a new code (re-coded) to further protect your privacy. This data, although re-coded, could potentially be used to identify you at some time in the future through advancing technology although this is considered to be very unlikely.

  We will do our best to protect your data and biospecimens during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data and biospecimens. In either case, we cannot reduce the risk to zero.

You will not receive any direct benefit from sharing your data and biospecimens. However, sharing your data and biospecimens may contribute to research that could help others in the future.

- **Pregnancy Test**: At the screening visit, you will be asked about your menopause status and whether you have had a menstrual period in the last 12 months. If you answer that you did have a period in the last 12 months, you will have to take a urine pregnancy test. If the pregnancy test is positive for pregnancy, you will be ineligible and will be excluded from study participation.

  Risks: There are no risks involved in performing a urine pregnancy test. Women who are pregnant or planning to become pregnant are excluded from the study.

Other Types of Risk to Consider

Risk to Confidentiality: While we will protect the confidentiality of the information you provide, confidentiality cannot be guaranteed. There is a chance that people outside of the research team may learn of your study participation.

Safeguards: The information collected for this research study will be accessible to authorized persons. Authorized persons include study team members, representatives of UConn Health; representatives of the American Urological Association (AUA, sponsor), the Urology Care Foundation (sponsor), the National Institute on Aging (NIA/NIH, sponsor) and representatives from Federal agencies when required by law, such as representatives from the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS). Representatives from these areas have access to the information so they may ensure that the study is being done correctly. They may also inspect the original medical/research records associated with the study.

John Dempsey Hospital Laboratory at UConn Health will be used to run the lab work on some of your blood samples. In order to process and track these lab results, the blood sample will include your name and Date of Birth and the results will be placed in your UConn Health medical record as well as in research records.

Paper research records will be kept in a secure location at Center on Aging, in a locked file drawer accessible only to authorized study personnel. Electronic research documents and files will be kept in password protected databases accessible only to authorized study personnel.

As previously described, and unless otherwise noted (eg, for blood work), all samples and data generated in this study will not be identified by your name or other personal identifiers, but rather will be given a unique study identification code. Paper research records will be kept in a secure location, and electronic research files will be kept on password protected and encrypted computers. A master key that links your name to your unique study identification code will be maintained in a separate locked secure location. Any study documents that contain your name, such as this informed consent form and HIPAA document, will be kept separate from your research records and locked in a secure location.

Any data that is shared with other researchers will be coded as described above to protect your identity and will not contain your name or any other personal identifiers. All data that is to be shared with the scientific community in online databases will not contain any personal identifiers and will be re-coded to further protect your identity.

By signing this consent, you provide the study PI and study coordinator permission to access your UConn Health medical record as it relates to your treatment and care for lower urinary tract symptoms, urological and gynecological conditions and care and other conditions/diseases that may affect your eligibility for and/or the outcome of this study. Information collected from your medical record will be kept confidential and used only for the purposes stated above (i.e., your eligibility for this study and how your medical conditions may have affected the study results). Blood safety lab results will be posted in your medical records and your medical record will reflect that you are involved in a research study. The medical record is confidential and accessible to authorized persons and to insurance companies.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality helps protect your privacy and the confidentiality of your data. With a Certificate of Confidentiality in place, the investigators cannot be forced to disclose research-related information about you to anyone not connected to the study, except in very limited circumstances. A Certificate of Confidentiality does not stop you from voluntarily disclosing information. It also does not stop the investigators from voluntarily reporting information about child or elder abuse, or reportable communicable diseases. The investigators on this study will report this information to State officials if it becomes known to them.
You should also know that:

- At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.
- A description of this research study 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 website at any time.

Possible Benefits from Participating

You will most likely not benefit directly from the information we gather in the study. There is no direct medical benefit to study volunteers from participation in this study. There is also the possibility that no benefit will come from this study. Others may benefit in the future from the knowledge we gain from this research.

Cost of Participating

You may have to take time away from your place of employment to come to the study appointments. You may incur some travel costs to get to study visits. There will be no costs to you for any study procedures, including the laboratory tests that will be conducted as part of this study or study medication you will take. If you are injured as a result of your participation you will be expected to pay for the cost of required medical care.

Payment for Participating

To compensate you for your time and effort in study participation, you will receive checks made to you at each study visit. If you complete all 3 study visits and this screening visit, you will receive a total of $250. You will only be paid for study visits you complete in the following installments: $25 for the screening visit, $50 for the completion of visit 1, $75 for completion of visit 2 and $100 for completion of visit 3.

You may be asked to sign a W-9 form. If you receive over $600 from participating in research studies over the course of the calendar year that money must be reported to the IRS. Your check will be made payable to you and no replacement check will be issued if it is lost or stolen. To issue your check, your name and social security number may go to accounts payable. Alternatively, you can choose not to receive any compensation.

Please indicate your preferences by initialing below:

You will accept compensation for this study _____

You prefer not to receive compensation for this study_____

This research may lead to the development of a commercial product that may have economic benefit to UConn Health. If such a product is developed, UConn Health does not intend to share the economic benefit with you.

Alternatives

You have the option not to participate in this study. You have the option to visit a urologist, which is a physician who specializes in bladder symptoms, to discuss FDA-approved medication for your condition, or other therapies that may or may not help improve your symptoms (bladder training, nerve stimulation, etc.)

Withdrawing from Participation

You can always choose to stop participating in this study. While we are doing this research, if we learn new information that may influence your decision about participation, we will share that with you. For example, if we learn about new risks we will share that information with you. If we think you need to know quickly, the researcher or study coordinator may call you or send you a letter. If we do not think you need to know quickly, we will tell you at your next visit. If you still want to participate, we may ask you to sign a new consent form.

You are free to stop taking part in this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you choose to withdraw, it will not adversely affect your relationship with your doctors or UConn Health. To withdraw you should send written notice to Iman Al-Naggar, PhD, UConn Health, 263 Farmington Avenue MC-5215, Farmington, CT 06030-5215.

The researcher may require that you be withdrawn from participation. This may happen if you do not adhere to the study protocol (that means if you do not follow the study instructions), including coming in for scheduled visits, participating in study phone calls, bringing the requested urine

samples and bladder diaries to each study visit, and taking the study drug regularly. Also, if you experience severe side effects or if blood or heart tests show it would be unsafe for you to continue the study protocol, the researcher may require that you be withdrawn from participation. If you are withdrawn or withdraw from the study, you will be asked to return all unused study drugs and answer a few questions about your experience with the study.

If you choose to withdraw from this study, the data and samples that have already been collected will continue to be used and remain in the study database. Investigators on this study may continue to review the study data collected prior to your withdrawal, and may consult public records, such as those establishing survival status.

Additionally, if you withdraw, are withdrawn by the PI, or stop taking the study drug within two weeks of a scheduled visit or call, you will be required to participate in the assessments for this visit and data collected from these visits will still be included in the study.

Sharing Information / Samples

Upon completion of the study, the samples will be kept in storage until fully utilized. The collected information and samples kept in storage beyond the end of the study will be coded as described above to protect your anonymity. These coded samples may be shared with other researchers and used in other projects. Because there will be no identifiers associated with the information/samples, additional consent from you will not be sought.

You agree to have your coded samples stored for use in future studies. Initial choice below:

____ Yes ____ No

Results of This Research

Unless you request a summary of the overall research findings at the end of the study, you will not be told any of the results of the research. Results will not be made available to you because they will not have relevance to your individual medical care. If you wish to obtain results from the lab bloodwork done at the screening visit or any other study visit, you may do so by requesting it in writing from Dr. Al-Naggar by sending her a written request addressed as follows: Iman Al-Naggar, PhD, UConn Health, 263 Farmington Avenue MC-5215, Farmington, CT 06030-5215.

Incidental Findings

In addition to the research we intend to do, it is possible that unexpected and/or unrelated information will be discovered that is not the focus of this study. This information will not be disclosed to you.

Adverse Events

If you experience an adverse event you should tell the principal investigator (PI) as soon as possible. You may contact Iman Al-Naggar, PhD by calling 860-679-4639 (office phone) or 860-534-1644 (cell phone) or the Co-Investigator, Dr George Kuchel by calling 860-670-6892. The study is blinded so the PI will not know what medication you are taking. If the PI determines the event is serious, unexpected, possibly related to the study drug, and medical intervention is needed, the PI will un-blind the data so that you receive proper treatment.

UConn Health does not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process contact a representative of the UConn Health Institutional Review Board at 860-679-8729 or 860-679-4849.

UConn Health does not offer free care. However, treatment for a research related injury can be obtained at Uconn Health for the usual fee.

Questions

The PI is willing to answer any questions you have related to the study. You are encouraged to ask questions prior to deciding whether or not to participate and throughout the course of your participation. For questions related to the research study, you may contact the Principal Investigator, Dr. Iman Al-Naggar at 860-679-4639 (Office) or 860-534-1644 (Cell) or by e-mail at alnaggar@uchc.edu.

If you have questions about your rights as a research volunteer you may contact a coordinator at the Institution Review Board at 860-679-8729, 860-679-4851, or 860-679-4849.

You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies.
Please do not call the IRB number for medical related issues or to schedule or cancel an appointment.

Please initial your choice for each question:

1. May we contact you for additional information for this study, if needed, even after the study ends?

   _____Yes _____ No

2. May we contact/invite you about participating in future research studies?

   _____Yes _____ No

Consent to Participation:

By signing this form, you (the participant) acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this study as described in this form. You acknowledge that you have the opportunity to voluntarily provide feedback about your experience as a research participant. You may ask for a copy of the Research Participant Feedback Form, you may obtain the form online at

https://ovpr.uchc.edu/services/rics/hspp/volunteers/, or you may submit the form online at https://redcap.link/UConnHealth-Feedback-Research.

By signing this form, the individual obtaining consent is confirming that the above information has been explained to the subject (and/or legally authorized representative, parents or legal guardians) and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form will be provided to the participant.

Role	**Printed Name**	**Signature**	**Date**	**Time**
Subject				
PI, Co-I, or research staff				
Impartial Witness (Only for visually impaired participants who were unable to read the ICF)				