Official Title: Prevention of Fall in Older Adults with Overactive Bladder

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UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM
Study Sponsor: Urology Care Foundation grant

Protocol Title:	Prevention of Falls in Older Adults with Overactive Bladder
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You are being invited to participate in a research study. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

Why am I being asked to volunteer?

You are being asked to volunteer because you are interested in medical treatment of overactive bladder and you are 65 years of age and over. Overactive bladder is a bladder condition involving a sudden urge to urinate, frequent urination, and often involuntary loss of urine associated with the urge to urinate (urge urinary incontinence), It affects many older adults and is associated with increased risk of falls.

What is the purpose of this research study?

Overactive bladder is often an indicator of muscle weakness, increased risk of falls, and decreased physical activity. The first-line treatment of overactive bladder is a type of medication called an anticholinergic agent. The purpose of this study is to evaluate the use of patient-reported questionnaires to assess relationships between preference for treatment with an anticholinergic agent, adherence to treatment, and effects of treatment on physical activity level, risk of falls, mental function (attention, memory, language, problem solving, decision making), and balance.

Participants in this study will receive therapy with fesoterodine, which is an FDA-approved anticholinergic medication that has few, mild side effects. This medication has been shown to be effective in decreasing symptoms of overactive bladder. Participants will be evaluated for changes in urinary symptoms, physical activity, mental function, and balance after 8 weeks of treatment with fesoterodine.

How long will I be in the study? How many other people will be in the study?

You will be in the study for 9 weeks.
A total of 80 subjects will be involved in this study, which will only be conducted at sites affiliated with Penn.

What am I being asked to do?

You will be asked to undergo screening to determine your eligibility to participate in this study. During a screening visit, you will complete a short questionnaire regarding your urinary symptoms. You will also undergo a pelvic examination and an ultrasound examination to determine how much urine remains in your bladder after you urinate.

If you choose to participate in this study, at a baseline visit one week later, you will be asked to fill out several questionnaires and perform simple balance tests to examine your abilities prior to the beginning of treatment. You will also be given an activity monitor (called an accelerometer) to track your daily physical activity for one week before you begin taking fesoterodine and for one week before you stop taking it. You will be given instructions for wearing the accelerometer at the time of enrollment in the study. At this visit, you will also undergo counseling on management of overactive bladder that you would have regardless of participation in the study. This visit should take approximately 1.5 hours.

At this time, you will receive a 90-day supply of fesoterodine, 4 mg, to be taken by mouth daily. You will start this medication 1 week after the baseline visit (after the week of wearing the accelerometer). All participants in the study will receive this medication. After 4 weeks, you will be contacted by telephone to review your response to fesoterodine, and the dose may be increased to 8 mg. The study doctor may also substitute a different anticholinergic medication if it seems necessary.

A follow-up visit will be scheduled 8 weeks after the start of medication treatment. Prior to this appointment, you will receive a phone reminder to wear the activity monitor for the week before this visit and to bring your medication bottle to the visit. At the follow-up visit, you will repeat the questionnaires and balance tests conducted during the baseline visit. This visit will take approximately 1.5 hours. You will again be given an accelerometer to track your daily physical

activity for one week after this visit. After this week, you will return the accelerometer. This concludes your participation in the study.

What are the possible risks or discomforts?

The risks from fesoterodine are generally mild.

Side Effects	
Most common (>4%, or affecting more than 4 out of 100 people)	• dry mouth (19 to 35%) • constipation (4-6%) • dry eyes (1-4%).
Less common (<4%, or less than 4 in 100 people)	Neurologic: • Insomnia (1%) Skin: • Rash (1%) Stomach and intestines: • Dyspepsia (heartburn) (2%) • Nausea (1% to 2%) • Abdominal pain (1%) Bladder: • Urinary tract infection (3% to 4%) • Dysuria (pain with urination) (1% to 2%) • Urinary retention (1%) Liver: • Elevated liver enzymes (1%) Muscles, bones: • Back pain (1% to 2%) Lungs: • Upper respiratory tract infection (2% to 3%) • Cough (1% to 2%) • Dry throat (1% to 2%) Others: • Peripheral edema (fluid in the limbs) (1%)
Uncommon (<1%, or less than 1 in 100 people)	Angina (chest pain) Angioedema (swelling under the skin) Diverticulitis (inflammation of the outpouchings in the wall of the colon) Gastroenteritis (stomach flu) Heat prostration (overheating of the body) Hypersensitivity reactions (allergic reaction) Irritable bowel syndrome QTc prolongation (heart rhythm disorder).

During the Berg balance scale test, which involves standing, sitting, and walking, there is a potential risk for falls. However, the test will be conducted with the oversight of a physician, and you are encouraged to speak up about concerns and stop if you feel that you might fall during the course of the testing.

Additionally, there is the potential loss of confidentiality; that is, someone could find out that you have participated in this study, and potentially any data on you that has been collected during the study. We will decrease this risk through the following: all data needed for the study will be stripped of any identifiers (such as name and medical record number) and associated with an assigned subject identification number only, so that it cannot be directly linked to you. Also, all files, forms, and any consent forms or any other documents that could link to you will be locked in a secure area at all times. Only investigators involved in this study will have access to these files

Research may involve risks that are currently unknown.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

This study may benefit you by improving your urinary symptoms.

Additionally, this study may provide future benefit by allowing us to improve questionnaires and tests used to measure physical activity, mental function, and balance for use in future studies. We may also be able to better understand the connections between treatment preference and adherence to anticholinergic therapy on physical activity and fall risk in older adults with overactive bladder, potentially providing improvement in quality of life and decreasing risks of falls for patients in the future.

What other choices do I have if I do not participate?

If you choose not to participate, you may be offered medical treatments (including fesoterodine) or surgical treatments for overactive bladder without being involved in questionnaires and physical activity measurement. By participating in this study, you may or may not be receiving the medication that would be selected for you by your physician per routine clinical care.

Will I be paid for being in this study?

You will receive compensation for travel costs (parking, transportation). You will also receive a payment of $50 ($25 at the time of the baseline visit and $25 at the time of the 8-week follow-up visit).

Will I have to pay for anything?

You will not have to pay for anything to participate in this study. A 90-day supply of fesoterodine will be provided without cost. Research visits (for questionnaires and tests) are provided without cost.

What happens if I am injured from being in the study?

Potential injuries include side effects from the medication. Although the risk of major side effects is minimal, if you experience harm from the side effects, you should contact the urogynecology on-call physician (215 662 4000) and seek care immediately from either your primary care physician or from the emergency room (if your situation is emergent), as advised by by the on-call physician. If you think you have been injured as a result of taking part in this research study, please report these injuries to the principal investigator (the person in charge of the research study) as soon as possible. The researcher's name and phone number are listed in the consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

When is the study over? Can I leave the study before it ends?

Your participation in the study is completed with the follow-up visit. The study is expected to end after all participants have completed all visits, and all information has been collected. This is expected to be approximately 1 to 1.5 years after the study starts. This study may also be stopped at any time by your physician or the study Sponsor without your consent because:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor or the study's Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Otherwise, only investigators and other personnel involved in the study and in routine patient care will be able to see or use your information. The Institutional Review Board at the University of

Pennsylvania will also have access to the records. Any information disclosed outside of the covered entity may not be protected.

Extensive efforts will be made to ensure and maintain security of PHI and maintain participant confidentiality.

During the study, any interactions with you will take place in a private room at the study doctor's office. Telephone calls will be conducted privately in the office setting.

Data will be recorded on forms identified with an assigned Subject ID number only. Your name, medical record number, or other identifiers will not be present on the data collection forms themselves. Any consent forms, record logs, data collection forms, or other information will be stored in a secure and locked filing system at all times. Data will be entered electronically into a password-secured database using Subject ID.

Electronic Medical Records and Research Results

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.
If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

What information about me may be collected, used or shared with others?

- Name, address, telephone number, date of birth
- Email addresses
- Personal and family medical history
- Medical record number
- Results from physical examinations, tests or procedures
- Records of office visits and telephone calls conducted for routine care
- Medical records related to illnesses or medical events that happen to you while you are in the study, if applicable

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right.

Who may use and share information about me?

The following individuals may use or share your information for this research study:
The investigator for the study and the study team
Clinical personnel who are part of your physician's office and part of routine care
Institutional Review Board at the University of Pennsylvania

Who, outside of the School of Medicine, might receive my information?

Institutional Review Board at the University of Pennsylvania
The U.S. Food and Drug Administration
The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.
Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent and HIPAA authorization form will be given to you.

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date
_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date