Amplifying Sensation in Underactive Bladder (AMPLIFY)

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Duke University Health System

Consent to Participate in a Research Study
ADULT
AMPLIFY: Amplifying Sensation in Underactive Bladder

Concise Summary

The purpose of this study is to learn how bladder and urethral sensory feedback can contribute to poor urination (emptying of the bladder) in women with underactive bladder. The information we learn by doing this study may help us develop new treatments for persons with incomplete bladder emptying.

Participants in this study will complete questionnaires about their bladder function, undergo routine bladder function procedures (urodynamic evaluation), and undergo procedures delivering electrical stimulation to the bladder and urethra (the tube from your bladder to the outside of your body). The study visit will take less than 4 hours. You will also be asked to complete a urinary symptoms questionnaire 7 days after your study visit.

There are risks of infection and irritation from catheterization, discomforting sensations from electrical stimulation, and loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in a research study about the effect of electrical stimulation on underactive bladder function. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of the salaries for the lead researchers and the research team will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Cindy L. Amundsen, M.D. will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn how bladder and urethral sensory feedback can contribute to poor urination (emptying of the bladder) in women with underactive bladder. There are two main parts to this study: 1) To evaluate improvement of sensations during bladder filling and emptying with electrical

stimulation to the bladder or urethra, and 2) To evaluate improvement of function during bladder emptying with electrical stimulation to the bladder or urethra.

Bothersome urinary symptoms and incomplete bladder emptying may involve reduced nerve activation in the bladder and urethra (the tube from your bladder to the outside of your body). We propose that electrical stimulation by an investigational device can increase sensory nerve activation to improve sensations of the bladder and improve bladder emptying function. The word "investigational" means the study device is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA).

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 25 people will take part in this study at Duke University Medical Center.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. After signing the consent form, you will be asked to fill out a demographics sheet. We will also test your urine to measure for infection and pregnancy.

You may not participate if you have normal voiding function (fully empty your bladder), have normal sensations or are not bothered by symptoms related to your bladder, are pregnant, or have an active infection in your urine. Provided that the exams do not demonstrate these results, you will then undergo a study procedure to evaluate sensations you feel in your urethra and bladder.

If you participate, you will be asked to stop taking medications for urinary dysfunction for 48 hours (washout period) prior to the study procedures.

A nurse or doctor will place a small tube (catheter with electrodes) in your urethra and an investigational device will deliver electrical stimulation to activate sensory nerves. You will be asked to indicate when you feel a sensation at 3 different settings (electrical frequencies). Once we record consistent values, a nurse or doctor will move the catheter into the bladder and perform the same test to activate bladder sensory nerves and record your responses. These two tests will take up to 30 minutes and you will be randomized (assigned by chance, like drawing names out of a hat) to receive bladder or urethra stimulation first.

We will use the values obtained from investigational sensory testing to deliver continuous electrical stimulation to your bladder or urethra. The location depends on which value is higher compared to normal. A nurse or doctor will once again place a small tube (catheter with electrodes) to perform this investigational study procedure to your bladder (up to 60 minutes) or urethra (up to 15 minutes). We will also place a surface patch on your abdomen to disperse the electrical current and reduce discomfort. Electrical stimulation to your urethra will occur during routine urodynamic evaluation when you urinate on a special toilet.

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Following the session of electrical stimulation, you will undergo the final study procedure to evaluate your bladder function (routine urodynamic evaluation) that is similar to standard bladder testing. A nurse or doctor will insert a small tube (catheter) through your urethra into your bladder to record the amount of pressure in your bladder and urethra. A catheter will also be placed in the vagina to measure the pressure in your abdominal cavity. This will give us information about your bladder, too.

It is also necessary to monitor the activity of the muscles in your pelvis that control the exit of your bladder (pelvic floor and urethral sphincter muscles) during bladder filling and emptying. Two surface patches (electrodes) will be placed at the 3 o'clock and 9 o'clock positions, 1 to 3 centimeters from the around the vaginal opening. These electronic sensors will record muscle activity while the bladder is contracting. These are standard urodynamic tests when evaluating an individual with incontinence (loss of control of urine).

Your bladder will be filled with a sterile saline solution, through the small tube that was placed inside the urethra. You will be asked to tell us about the sensations you are feeling while we fill your bladder. When your bladder is full, we will ask you to urinate on a special toilet. We will then check how much urine is left in your bladder by removing the first tube and inserting a small catheter into the bladder through the urethra.

Seven days after your study procedures, you will also be asked to fill out an online questionnaire at home about your urinary function for the past week.

This research study is voluntary and includes only people who choose to take part. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you do not sign this consent form, you will continue to receive care, but not as a part of this study. If you agree to be in the study, you may also withdraw from the study at any time.

HOW LONG WILL I BE IN THIS STUDY?
The total study duration will be 1 week. Your study procedure visit will be less than 4 hours. You will also be asked to complete a urinary symptoms questionnaire at home 7 days after your study visit (about 10 minutes long).

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

- There is a slight risk of bladder infection from the catheterization involved in these tests. If you have an infection, you may experience urinary frequency (having to urinate more often), burning during urination, and/or a foul odor to your urine. This risk is estimated at about 5% (less than 2

out of 25 people). The risk will be minimized by using a sterile technique for catheterization and lubricating the catheter with K-Y jelly. If you develop symptoms of a bladder infection as a result of the study procedure, the study doctor will assist with evaluating and prescribing antibiotics as necessary.

- There is a slight risk of irritation to the urethra as a result of inserting catheters into the bladder. This risk is estimated at less than 5% (less than 2 out of 25) and will be minimized by careful catheterization technique performed by experienced clinical staff.
- There is a risk of discomforting sensations from electrical stimulation to the bladder and urethra. You can elect to decrease or terminate stimulation at any point during the study. We will minimize the risk of activating nerve fibers carrying painful stimuli by individually adjusting current amplitude to 80% of your maximum tolerable intensity.
- There is a slight risk of skin irritation from the patches applied to the skin for electrical recordings or from the gel used to apply the patches. This will be minimized by using patches that are not known to cause an allergy, and by using gel that is commonly used for other types of electrical recording.
- You will be asked to refrain from taking any medications for urinary dysfunction for 48 hours (washout) prior to participating in these procedures and stopping these medications may make your symptoms worse. You can resume taking your medications immediately after completion of your participation.

Reproductive Risks
The effects of the study procedures on pregnancy are not known, and the changes your body undergoes during pregnancy might affect the results of some of the tests. Therefore, pregnant women are not allowed to participate in this study. If you could possibly become pregnant (you have not completed menopause, or you have not had a hysterectomy and/or both tubes and/or both ovaries removed) and you have a partner who is able to father children, a urine pregnancy test will be done prior to the procedures and it must be negative before you can continue in this study.

Risks of Washout:
During the period when you are required to withdraw from medications that affect your urination (washout period), your lower urinary tract symptoms may get worse. Please discuss the washout period with the study doctor.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefit to you. Based on preliminary data from previous participants, it is observed that some subjects experience a reduction in bothersome voiding dysfunction symptoms. This observation is derived from a symptom questionnaire completed one week after the stimulation session. We hope that in the future the information learned from this study will benefit other people with your condition.

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WHAT ARE THE ALTERNATIVES TO PARTICIPATING IN THE STUDY?

If you choose not to participate in this study, or if you are ineligible, there are alternative options available for managing your underactive bladder symptoms. It is important to discuss these alternative options with your healthcare provider to determine the most suitable course of action based on your individual needs and preferences. These alternatives may include:

1. Continuing current urogynecologic recommendations: your healthcare provider may recommend continuing intermittent self-catheterization, continuing antibiotics for the prevention of urinary tract infections, or scheduled voiding.
2. Exploring other treatment options: you may discuss alternative options with your healthcare provider such as medications, physical therapy, or surgical interventions depending on your specific symptoms and medical history.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests and procedures may be reported to the National Institutes of Health (NIH) and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the NIH, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain tests and/or procedures performed. Some of these tests and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the research data office at Duke or representatives and affiliates of NIH. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with

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Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Em Abbott, Dr. Warren Grill, or Dr. Cindy Amundsen. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

The study sponsor National Institutes of Health has agreed to pay for services and procedures that are done solely for research purposes. Please talk with the PI/study team about the specific services and procedures (including the device, if applicable) that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

Taking part in this study may cost you and/or your insurance company more than the cost of getting regular medical treatment. These costs may include treatment for urine infection from research-related procedures, like catheterization.

WHAT ABOUT COMPENSATION?
Compensation is pro-rated as follows:

- $20 for completing informed consent
- $60 for completing any part of the procedure visit
- $60 for completing the entire procedure visit
- $60 for completing the final questionnaire

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Cindy Amundsen at (919) 684-8111 during regular business hours and after hours and on weekends and holidays ask that she be paged.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

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Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Em Abbott in writing and let them know that you are withdrawing from the study. His mailing address is Duke University, Department of Biomedical Engineering, Box 90281, Durham NC 27708-0281.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

Your study procedure data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Em Abbott at (919) 660-5299 during regular business hours or by email at em.abbott@duke.edu after hours and on weekends and holidays. For questions about a research-related injury, contact Dr. Cindy Amundsen at (919) 684-8111 during regular business hours and after hours and on weekends and holidays ask that she be paged.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time