A Randomized Trial Comparing Continence Pessary to Continence Device (Poise Impressa®) for

Stress Incontinence: Informed Consent

NCT03174431

10/25/2021

**Consent to Participate in Research and HIPAA Research Authorization**

**Study Title:** A Randomized Trial Comparing Pessary to Continence Device (Poise Impressa) for Stress Incontinence

**Principal Investigator:** Andrew Hundley, MD

**Sponsor:** The Ohio State University Wexner Medical Center

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

**1. Why is this study being done?**

Stress urinary incontinence (SUI) is a common condition that many women deal with. It is a condition where you have accidental urine leakage from the bladder caused by certain types of activities, like coughing, laughing, sneezing, and exercise. This study is comparing 2 non-surgical devices for the management of this condition.

You will receive either a continence pessary or an over-the-counter FDA approved intravaginal device.

A continence pessary is a flexible device made from silicone. Your health care provider will place this device in the vagina. It helps support the neck of the bladder to help decrease or stop urinary leakage that is caused by activities like coughing, laughing, sneezing, and exercise. This device comes in different shapes and sizes in order to provide the most comfort. They can be removed and placed by the patient or their healthcare provider. These devices can be left in the vagina for at least a month before it needs to be removed and cleaned with soap and water. You can use it while you are on your period. This device needs to be removed for sexual activity.

The over-the-counter FDA approved intravaginal device comes in 3 different sizes that you can insert into the vagina to help decrease or stop urinary leakage. This device is made of a non-absorbable material. It is inside a device that looks like a tampon applicator so you can easily place and remove the device yourself. This device can be worn for 12 hours out of a 24-hour period. This device cannot be used during sexual activity or when you are on your period.

**2. How many people will take part in this study?**

We will enroll 138 patients into this study.

**3. What will happen if I take part in this study?**

If you choose to participate in this 4-week long study, we will ask you to do the following:

<u>At enrollment:</u>

- Complete 4 questionnaires about your urinary leakage. These questionnaires help us determine how your urinary leakage is impacting your quality of life. You will also complete a short questionnaire about your demographic information, such as your race, ethnicity, and insurance. This should only take about 15-20 minutes.

- We will be checking your urine at the beginning of your visit to make sure that you do not have a bladder infection. We check this on all of our patients that visit the office. If you have an infection we will make sure that you receive the correct treatment and evaluation. Once your infection is gone, you will be able to start the study.

- If you are having periods and have the ability to get pregnant, we will give you a urine pregnancy test. We will provide you with a pregnancy test as part of the study and will not be charged for this.

- You will fill out a 3-day bladder diary at home so that we can see how often you use the restroom and when you leak urine. This diary is routinely done when we see patients with urinary leakage problems. You will bring this diary with you to your next visit.

- You will be randomly selected to either receive the continence pessary (current standard of care) or the over-the-counter intravaginal device. The study nurse will tell you at your next visit which device you have been selected to use. We will schedule your next visit before you leave the office.

<u>Intervention visit: (approximately 20 minutes)</u>

- The study nurse will tell you which device you have been selected to use.
    - If you have been selected to use the continence pessary (standard of care), a health care provider will select the best shape and size for you to use. The provider will teach you how to take the device out and put it back in so that you can do this at home. You can leave this device in for a month before having to take it out to clean it. You can also use this device while you are on your period if you want to. You will need to remove this device during sexual activity.

Example of a continence pessary

- If you have been selected to use the over-the-counter intravaginal device, the study nurse will give you a sizing kit that has 3 different sizes. You will be given the patient information sheet with instructions on how to use the device. You will try the different sizes in the office to see which one works best for you. Once you have picked out your size, the nurse will give you a 14-day supply. You cannot use this device during your period. You will also need to remove this device during sexual activity. The manufacturer recommends that use this device for no more than 12 hours in a 24-hour period.


Example of over-the-counter intravaginal device

- At this visit we will make an appointment for you to return in 2 weeks. Once you get home, if you feel that the device you have been given does not feel comfortable, is falling out, causing vaginal bleeding not related to your period, or if you have any other concerns please call the phone number for the study contact. They will likely have you take the device out and they will make an appointment for you to see a health care provider in the office.

Week 2 visit: (approximately 20 minutes)

- All participants will complete a short questionnaire asking about how you are using the device and your satisfaction with the device. The study nurse will also ask you about any problems that you may be having with the device.

- If you are using the pessary, you will need a pelvic exam to make sure that the device is fitting correctly and is not causing any problems, such as vaginal bleeding, vaginal infection, or superficial cuts. The chance of having a problem is unlikely. This exam is normally done on all of our patients using this device.

- If you are using the over-the-counter intravaginal device, the study nurse will ask you if you feel that the size that you have been using at home feels ok. If you think you need a different size, you can try more sizes in the office and pick a different size. You will get another 14-day supply of the size you picked. If you feel like you are having problems, such as vaginal discharge, vaginal bleeding, or pain, a healthcare provider will do a pelvic exam to check for any potential problems. Otherwise, you will not have an exam at this visit.

- At this visit, all participants will be given another 3-day bladder diary to complete at home before their final visit. You can complete this during week 3 or 4. We ask that you complete this diary during the days that you are using the device.

Week 4 visit: End of study visit (approximately 45 minutes)

- You will bring in the completed 3-day bladder diary that you were given at your week 2 visit.
- During this visit all participants will have a pelvic exam to look for any potential problems that the device might have caused. Examples of possible problems could be a vaginal laceration, vaginal bleeding, or a vaginal infection. These are all uncommon problems.
- You will complete 4 questionnaires about your urinary leakage to see if the device helped your urinary leakage problem and quality of life. These questionnaires are similar to the ones that you completed at the beginning of the study.
- You will receive a $10 gift card for participating in our study at this visit.
- At the end of the visit we will give you information on the other device that you were not selected to use.
    - If you were using the over-the-counter device and want to use the continence pessary instead we will make a routine appointment for you to have this done. That visit will not be part of the study.
    - If you were using the continence pessary and would like to try the over-the-counter intravaginal device, we will give you information on how to purchase the devices. We do not normally give these devices to our patients since they are available over-the-counter.
    - If you decide that you do not want to try to manage your urinary leakage with a non-surgical device we can make an appointment for you with the health care provider to review all available options. This may include pelvic floor physical therapy or surgery.

Post Study Follow Up

- You will receive a follow up telephone call from one of the study coordinators 6 months and up to 1 year after you have completed participation in the study. They will ask you 2 brief questions about whether or not you are continuing to use the device you were selected to use."

**4. How long will I be in the study?**

You will be in this study for 4 weeks from the time that you receive your device.

If you are eligible for this study, your enrollment process will take about 15 minutes. We will go over the study with you and give you 4 questionnaires to fill out.

The first and second visit will take about 20 minutes for each one. The last visit of the study will take about 45 minutes.

You may need additional visits during the study if you feel like you are having problems related to the device you are using. A healthcare provider will see you at this visit and it may take up to 30 minutes.

At the end of the study, you can decide to go with other treatment options for your urinary leakage. We will make a routine appointment with the healthcare provider so that they can talk to you about options they think would be appropriate for you.

**5. Can I stop being in the study?**

You may leave the study at any time. Upon leaving the study, we will give you information about the device you were not selected to use during the study. We will also give you information about other management options that may be available to you. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

**6. What risks, side effects or discomforts can I expect from being in the study?**

There are very few risks involved with participation in this project. One small risk is a breach of your privacy or the confidentiality of your data. We have numerous safeguards in place, however, to ensure that doesn't happen. Some infrequent associated risks that have been reported are mild vaginal discomfort, vaginal spotting, vaginal infections, and urinary tract infections. No serious adverse events have been reported.

**7. What benefits can I expect from being in the study?**

You may or may not receive any personal benefit from your participation in the study. If it turns out that the intervention is effective, it might help you with management of your stress urinary incontinence.

**8. What other choices do I have if I do not take part in the study?**

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. Your provider will discuss the appropriate options available to you regarding your condition. Available options will be dependent on your health and severity of your condition and can vary from patient to patient.

Your options may include pelvic floor physical therapy and/or surgery. Pelvic floor physical therapy is a non-surgical option that requires you to see a physical therapist that specializes in pelvic floor problems. They can teach you different exercises to help strengthen the muscles that help support your bladder. This type of therapy can be a useful option for patients with mild urinary leakage and have the ability to see a therapist on a regular basis. There are different types of surgery available but not all options may be right for you. Your health care provider can talk to you about surgery options that you may be a candidate for.

**9. What are the costs of taking part in this study?**

There will be no direct cost for you to participate in the study. The standard of care for a nonsurgical device for the management of your type of urinary leakage is a continence pessary. If you receive the continence pessary, your insurance will be billed as it normally would for a patient using this device. This includes the cost of the device and the follow up visits. It is common practice to have the patient return to the office for the pessary to be placed by a health care provider and to have at least 1-2 follow up visits in the first month after the device is placed. This is to make sure you are comfortable and the device is fitting properly. There may be a co-pay for your fitting visit and week 2 visit, depending on your insurance. If you receive the over-the-counter intravaginal device, your follow up visits are related to the study (intervention visit, week 2, and week 4) and will not be charged. This is because we do not currently use this device for standard treatment. Any visits that are for routine standard of care will be a billable visit. .

**10. Will I be paid for taking part in this study?**

Upon completion of the study, you will receive a $10 gift card.

Law considers payments to participants taxable income.

**11. What happens if I am injured because I took part in this study?**

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

**12. What are my rights if I take part in this study?**

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

**13. Will my study-related information be kept confidential?**

Your information will be kept confidential and only members of this research study will be able to contact you. We will only use the information that you are asked to provide for analysis and publication.

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

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 the website at any time.

**14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

**I. What information may be used and given to others?**

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
- Records about the study device; and

**II. Who may use and give out information about you?**

Researchers and study staff.

**III. Who might get this information?**

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;

**IV. Your information <u>may</u> be given to:**

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

**V. Why will this information be used and/or given to others?**

- To do the research;
- To study the results; and
- To make sure that the research was done right.

**VI. When will my permission end?**

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

**VII. May I withdraw or revoke (cancel) my permission?**

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. 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 researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

**VIII. 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 and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

**IX. Is my health information protected after it has been given to others?**

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

**X. May I review or copy my information?**

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

**15. Who can answer my questions about the study?**

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Andrew Hundley, MD or Silpa Nekkanti, MD at 614-293-4643.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact Jennifer Elliott at 614-685-6100 or email her at Jennifer.Elliott2@osumc.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Andrew Hundley, MD or Silpa Nekkanti, MD at 614-293-4643.

**Signing the consent form**

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

| | |
|---|---|
| **Printed name of subject** | **Signature of subject**<br>**AM/PM**<br>**Date and time** |
| **Printed name of person authorized to consent for subject (when applicable)** | **Signature of person authorized to consent for subject (When applicable)**<br>**AM/PM** |
| **Relationship to the subject** | **Date and time** |

**Investigator/Research Staff**

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

| | |
|---|---|
| **Printed name of person obtaining consent** | **Signature of person obtaining consent**<br>**AM/PM**<br>**Date and time** |

**Witness(es) -** May be left blank if not required by the IRB

| | |
|---|---|
| **Printed name of witness** | **Signature of witness**<br>**AM/PM**<br>**Date and time** |
| **Printed name of witness** | **Signature of witness** |

_____ **AM/PM**

**Date and time**