Consent Form

Study Title: Assessment of effectiveness and safety of a novel pessary for the non-surgical management of pelvic organ prolapse

NCT Number: NCT04508335

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Dartmouth-Hitchcock

Permission to Take Part in a Human Research Study

IRB APPROVED
AS MODIFIED
Oct 05, 2022

Dartmouth Hitchcock Medical Center

TITLE:	Assessment of effectiveness and safety of a novel pessary for the non-surgical management of pelvic organ prolapse
PROTOCOL NO.:	CP-002-01 WCG IRB Protocol #20211208 STUDY02000676
SPONSOR:	Reia, LLC
INVESTIGATOR:	Kris Strohbehn, MD One Medical Center Drive Lebanon, New Hampshire 03756 United States
STUDY-RELATED PHONE NUMBER(S):	Dartmouth-Hitchcock Medical Center 603-653-9312 (direct phone number for the study doctor) 603 650-5000 (24 hours – ask to speak with the Urongynecologist on call)

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being asked take part in a research study because you currently use a Gellhorn or ring style pessary to manage pelvic organ prolapse.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
The purpose of this research is to test the function, effectiveness, and safety of an investigational vaginal pessary that is under development and is intended to be used for the management of pelvic organ prolapse.

How long will the research last and what will I need to do?
If you decide to take part in this research study, we expect that your participation will take approximately 4 months. If you typically have pessary appointments every 3-4 months, it will require 1-2 visits, which you would not ordinarily need to attend. After the first month, your current pessary will be exchanged for a study pessary to be used for the remainder of the study. You will be asked to fill out questionnaires.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?
The most common risks of any pessary include discomfort associated with insertion, removal, or use of the pessary. You could also experience increased vaginal discharge or vaginal bleeding from irritation of the vaginal skin. It is possible that you could experience any of these even if your current pessary has not caused them in the past.

More detailed information about the risks of this study can be found later in this form in the section called, ***"Is there any way being in this study could be bad for me? (Detailed Risks)."***

Will being in this study help me in any way?
There are no immediate benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this study. You and others may be able to use a version of the study pessary in the future if it is cleared by the FDA and becomes available for use.

What happens if I do not want to be in this research study?
Participation in this research is completely voluntary. Your alternative to participating in this research study is not to participate. If you choose not to participate in this research, you will receive the usual ongoing care for your current pessary. You can choose not to participate or later to quit participating without penalty or loss of benefits to which you are otherwise entitled.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?
In the event of an emergency, dial 911 immediately.

If you require emergency health care, be sure to tell the emergency care provider that you are in this study. Let the study doctor or study staff know about your emergency care when possible.

If you have questions, concerns, or complaints about this study or need to report a study related injury or illness, you can call the study doctor or research director for this study at any time at the phone numbers on page 1 of this form. If the study doctor or research director is not available, other clinicians will be available to answer your questions at any time.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289, researchquestions@wcgirb.com if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be in this study?

We expect at least 50 people will be in this research study.

What happens if I say yes, I want to be in this research study?

If you decide to take part in this research, there will be a total of 3-4 visits including this one. If you are typically seen every 3-4 months, the last visit will be scheduled at the normal time you would next be seen for a pessary visit and there will be a total of 1-2 extra visits that would not normally occur. These additional visits will require extra time and travel.

You will continue to use your current pessary when you go home today.

In one month, you will return to be fit with a study pessary. At that time, you will go home wearing a study pessary instead of your current pessary. We will gather information about your current pessary, any problems it causes for you, and your general medical history. You will be asked to complete questionnaires relating to your prolapse and its effect on your day-to-day life.

You will then be scheduled for an in person visit one to three weeks later to ensure the study pessary is not causing complications for you. You will receive a phone call just prior to this visit. If you are doing well without any study related concerns, you and your practitioner can decide if this visit can be omitted. If your study pessary has fallen out, the in person visit will be kept and you will be refit with a new one.

If all is well, you will continue to use the study pessary until the end of the study, which is a total duration of 3 months. The table below summarizes this information.

Visit #	Week	Purpose	Would visit normally occur?	Length of visit
Today's visit	Today	Information gathering, physical exam (similar to your regular pessary visits)	Yes (unless you consistently self-manage)	1 hour
1	~1 month	Information gathering, physical exam, removal of your current pessary, fitting of study pessary	No	1 hour
2*	~1.5 months	Phone check-in on the study pessary. If in person visit is necessary, physical exam to check that the study pessary is not causing complications, refitting of study pessary if necessary.	No	45 minutes
3	~4 months	Information gathering, physical exam, removal of study pessary, reinsertion of current pessary, end of research study.	Yes (unless you consistently self-manage)	1 hour

*In person Visit 2 may be optional at the discretion of your provider.

Your visit will occur in the Urogynecology Division at Dartmouth-Hitchcock Medical Center.

What are my responsibilities if I take part in this research study?

Your responsibilities as a person taking part in this study

(1) Be aware it is important for your safety that the research team knows about your medical history and current condition.
(2) Notify the research team in advance if you plan to undergo any other medical treatment during this study, or are taking or plan to start taking any medications.
(3) Notify the research team if you suffer any injury or reaction, whether or not you think these problems are related to the study drug or procedures.
(4) If possible, seek treatment with the help of the research team if you suffer any injury or reaction, whether or not you think these problems are related to the study drug or procedures.
(5) Make reasonable efforts to cooperate with the instructions of the research team.
(6) Tell the study doctor or study staff if you want to stop being in the study at any time.

What happens if I say yes now, but I change my mind later?

You can leave the research at any time and it will not be held against you. You can inform the study doctor at any time if you decide to leave the research.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there a possibility being in this study could be bad for me or harm me? (Detailed Risks)

The potential risks to you for participating in this research may include:

- Discomfort during insertion, use, or removal of the study pessary.
- Minor abrasion with insertion or removal of the study pessary.
- Vaginal bleeding caused by the study pessary.
- Increased vaginal discharge caused by the study pessary.
- Difficulty urinating or leakage of urine caused by the study pessary.
- Embarrassment if the study pessary falls out while walking or using the bathroom.
- Vaginal irritation from using the study pessary.
- Inconvenience caused by the inability of the study pessary to support your prolapse.
- Loss of confidentiality if study records are lost or stolen.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

Potential added costs:
Taking part in this research study may lead to added costs to you. The sponsor will pay for all study visits. You and your insurance company will be charged for usual care a doctor would recommend for your condition which are not part of the study. You or your insurance plan will be expected to pay for the costs of this usual medical care.

For assistance in determining your insurance coverage, please call the billing specialist in DHMC Patient Financial Services. Please ask the research nurse or study doctor for a contact name and phone number. Please provide the billing specialist with the protocol number CP-002-01.

Sponsor information: The sponsor of this research is Reia, LLC. If you develop an illness or have an injury because you are in this research study, Reia, LLC will pay for the reasonable costs of medical treatment. The sponsor will not offer to pay for:

- Treatment of illness or injury that results from the negligence of a health care provider, or
- Treatment of a condition that you had before you were in the study.

The sponsor will not offer any other payments for your study-related illness or injury such as lost wages, expenses other than medical care, or pain and suffering.

Local Information: If you are injured or become ill as a result of research procedures, you will be provided with medical treatment, but the following organizations do not plan to pay for this treatment:

- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- Trustees of Dartmouth College
- Federal funding agency

If you have any questions or concerns about the legal responsibility of these organizations, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at (603) 650-1250 during normal business hours.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include: the IRB, the sponsor (Reia, LLC, the company developing the study pessary), government agencies (such as the Food and Drug Administration (FDA) and the Department of Health and Human Services), and other representatives of these organizations.

If the sponsor (Reia, LLC) pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.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.

Federal law provides additional protections of your medical records and related health information. By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study at Dartmouth Hitchcock Medical Center and elsewhere. You also permit any health care provider holding health information needed for this study to give copies of your information to the research team.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- The Dartmouth-Hitchcock Health Institutional Review Board (D-HH IRB)
- The other hospitals and medical centers taking part in this study
- WCG Institutional Review Board (WCG IRB)
- The Food and Drug Administration (FDA)
- Other operating divisions of The Department of Health and Human Services

In order to conduct this study, researchers need to use your health care information. This data is called Protected Health Information ("PHI"). PHI is protected by federal privacy laws (HIPAA). By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. There is no intention to disclose your PHI to others outside of the study. There are protections in place to keep your PHI and research data confidential. However, HIPAA requires notification so you are aware that if your PHI is disclosed to others, it may no longer be protected by federal privacy laws.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Identifiable data collected for this study will be used for research purposes which are determined to be reasonable and in line with expectations by a review committee.

Once data collected for this research study is no longer identifiable, the data may be used or disclosed for other purposes.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. You have a right to receive a copy of the information in your medical record at any time.

Your name, address, and social security number may be given to an office at DHMC that arranges for payments and reports payments to the IRS.

You can cancel this authorization at any time by giving a written notice to the study doctor. If you cancel this authorization, then you no longer will be able to participate in the study, and the information that has been collected prior to canceling the authorization may still be used and disclosed to the above-mentioned parties.

If you do not allow use of your health information for this study, you may not take part in this study.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- You are found to have a condition that does not allow participation in this research. For example, it is possible that a condition found during a physical examination could exclude you from this study.
- You have a reaction that requires immediate removal of the study pessary.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

- This research is being funded by Reia, LLC.
- If you need medical care because of taking part in this research study, contact the study doctor and medical care will be made available. Generally, this care will be billed to you, your insurance, or another third party. None of the institutions participating in this study have programs to pay for medical care for research-related injury. If you develop an illness or have an injury because you are in this research study, Reia, LLC will pay for the reasonable costs of medical treatment.
- If you agree to take part in this research study, we will pay you $300 for your time and effort. The payment, in the form of $100 gift cards, will be offered at the end of each of the three visits described above after this one. You will still receive a gift card for Visit 2, even if an in person visit does not take place. Your name, address, and social security number will be given to an office at Dartmouth-Hitchcock Medical Center (DHMC) that arranges for payments and reports payments to the Internal Revenue Service (IRS). If you do not provide a social security number, no payment can be made. This DHMC office sometimes checks to make sure that social security numbers and names match.
- Instead of being in this research study, you may choose not to participate. If you choose not to participate, you will receive the usual ongoing care for your current pessary.
- Data collected from this study may be used to create products or to deliver services, which may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date