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AS MODIFIED
Dec 10, 2020

Early Feasibility Prospective Open-Label Study to Assess the Function of a Novel Pessary for the Non-Surgical Management of Pelvic Organ Prolapse

Protocol Number:	CP-001
NCT Number:	NCT04275089
Sponsor:	Reia, LLC ("Reia") 331 River Road Lyme, NH 03768
Medical Monitor:	Paul Hanissian, MD 331 River Road Lyme, NH 03768
Principle Investigator:	Kris Strohbehn, MD
Study Site:	Department of Obstetrics and Gynecology Dartmouth-Hitchcock Medical Center One Medical Center Drive Lebanon, NH 03756 Kris.Strohbehn@Hitchcock.org Direct phone number for office of the PI: 603 653-9312 24-hour phone number: 603 650-5000

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TITLE: Early Feasibility Prospective Open-Label Study to Assess the Function of a Novel Pessary for the Non-Surgical Management of Pelvic Organ Prolapse

PROTOCOL NO.: CP-001
WIRB® Protocol #20201498
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SPONSOR: Reia, LLC

INVESTIGATOR: Kris Strohbehn, MD
1 Medical Center Drive
Lebanon, New Hampshire 03756
United States

STUDY-RELATED PHONE NUMBER(S): 603-653-9312
603-650-5000 (24 hours)

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?

We invite you to take part in a research study because you currently use a ring style or a Gellhorn 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 and comfort of a vaginal pessary that is under development and is intended to be used for the treatment of pelvic organ prolapse.

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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 less than one hour during a single visit. Your current pessary will be removed and you will be fitted with a research pessary for temporary use. You will be asked to dress, walk up and down the hall, use the bathroom, and return to the exam room so that the position of the research pessary can be determined before your current pessary is replaced. If the initial research pessary falls out, the process will be repeated with a research pessary of the next larger size. We will ask for feedback regarding comfort during insertion, use, and removal of the research pessary compared to your current pessary. The care that takes place during your typical pessary maintenance visit will be provided as well.

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?

Insertion and removal of any pessary can cause discomfort. The most important risk or discomfort that you may expect from taking part in this research would be associated with insertion or removal of a research pessary.

More detailed information about the risks of this study can be found under ***"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 benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits include the ability to use the research pessary or a modified version of the research pessary 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 to not participate in this research, you will receive the usual ongoing care for your current pessary.

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

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Dartmouth-Hitchcock Medical Center. The contact information is below:

Direct phone number for the study doctor: 603-653-9312
24-hour phone number (ask to speak with the Urogynecologist on call): 603-650-5000
Dartmouth-Hitchcock Medical Center

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One Medical Center Drive
Lebanon, NH 03756
USA

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 (800) 562-4789, help@wirb.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 a total of 15 people will be in this research study, which will take place solely at Dartmouth-Hitchcock Medical Center.

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

If you decide to take part in this research, you will be fitted with a research pessary for temporary use after checking the position of and then removing your current pessary. You will be asked to dress, walk up and down the hall, use the bathroom, and return to the exam room so that the position of the research pessary can be determined before the research pessary is removed and your current pessary is replaced. If the initial research pessary falls out, the process will be repeated with a research pessary of the next larger size. We will ask for feedback regarding comfort with insertion, use, and removal of the research pessary as well as your current pessary. Information from your medical chart (such as the size of your prolapse and your history of previous surgeries) will be collected to understand how those factors affect the function of the research pessary.

The research pessary is investigational, which means that it is not cleared by the Food and Drug Administration (FDA). The information collected in this study will not be used for future research, but there may be a second study in which the research pessary is used at home for 3 months, which you could qualify for if you are interested in participating. The research pessary or a modified version of the research pessary could be commercially available in the future.

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

If you take part in this research, you will be responsible to:

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 immediately if you suffer any injury or unexpected reaction to the

study pessary.

(3) Seek treatment with the help of the research team if you suffer any injury or unexpected reaction to the study pessary.

(4) Make reasonable efforts to follow the instructions of the research team.

What happens if I do not want to participate or if I say yes, but I change my mind later?

You can decide not to participate or you can leave the research at any time and it will not be held against you. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. If you decide to leave the research prior to the study visit, contact the investigator so that the investigator can unenroll you. You can inform the investigator at any time if you decide to leave the research during the study visit.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator 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 a research pessary.
- Minor abrasion with insertion or removal of a research pessary.
- Embarrassment if a research pessary falls out while walking or using the bathroom.
- Vaginal irritation arising from a research pessary.
- 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.

Taking part in this research study may lead to added costs to you. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

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 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.

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) 653-1250 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 research 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 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, 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)
- Western Institutional Review Board (WIRB)
- 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.

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 which does not allow participation in this research, such as a

finding upon physical examination that excludes you from this study.
- You have a reaction that requires immediate removal of a research 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 investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. The Dartmouth-Hitchcock Clinic has no program 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 $100 for your time and effort. The payment, in the form of a gift card, will be offered at the end of your visit.
- 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	