STUDY INFORMATION FOR RESEARCH SUBJECTS

CONSENT AND AUTHORIZATION FORM FOR RESEARCH

TITLE: Fractional Handpiece with CO2 Laser: Fractional Ablative Laser Treatment of Vulvovaginal Atrophy

PROTOCOL NO.: 2016-PM-001
WIRB Protocol# 20161370

SPONSOR: Perigee Medical

INVESTIGATOR: Sherry Thomas, MD, MPH
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STUDY-RELATED PHONE NUMBER(S): Sherry Thomas, MD, MPH, FACOG
(818) 480-7100 (24 Hours)

INTRODUCTION

A person who takes part in a research study is called a “research subject.” The use of “you” in this consent form refers to you as the research subject. The study Investigator will be called the “study doctor” throughout this consent form.

SUMMARY

We are asking you to be in a research study. This consent form will help you decide if you want to be a subject in this research study. Please read this consent form carefully and completely. Ask us to explain anything that you do not understand. You should not join this study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help people in the future.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctors will continue to treat you.
- Information from your medical records will become part of the research record. Your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study. This information will be anonymous and only known to the sponsor, Dr. Sherry Thomas.
- Your medical insurance will be billed for any standard medical care you receive during the research study.
- If you take part in this research study, you will be given a copy of this signed and dated consent form.

BACKGROUND AND PURPOSE OF THE STUDY

The study Investigator is asking you to participate in this study because you have a condition called vulvovaginal atrophy or "VVA". VVA is an inflammation of the vagina (and the outer urinary tract) due to the thinning and shrinking of the tissues, as well as decreased lubrication. These symptoms are due to a lack of the reproductive hormone estrogen. The most common cause of vaginal atrophy is the decrease in estrogen which happens naturally during perimenopause, and increasingly so in post-menopause.

The purpose of this study is to evaluate the use of a CO2 laser (Edge™ CO2 Laser) with a fractional handpiece made specifically for the vagina to possibly restore the normal physiological conditions of the vagina, thus reducing the symptoms of VVA. The Edge™ CO2 Laser and general fractional handpiece is approved by the FDA for ablative skin resurfacing (for example, treating fine lines and wrinkles, acne and surgical scars, skin pigmentation and discoloration, sun damage, pre-cancerous as well as benign lesions and uneven skin texture). The fractional handpiece used in this study for the treatment of VVA is experimental and has not been approved by the FDA for vaginal dryness associated with menopause.

RESEARCH SUBJECTS AND STUDY DURATION

Approximately 30 post-menopausal, female subjects are expected to be in this study. The length of time you participate in the study will be 10 weeks with a follow-up visit approximately 10 months from the start of your participation.

PROCEDURES

Below is a description of the procedures that will take place at study visits. Please ask the study doctor to explain any procedures you do not understand.

Baseline Visit (Week 0)

After obtaining your informed consent, the following screening procedures and assessments (evaluations) will be done to see if you can participate in this study (this visit should take about one hour):

- Review of medical records for medical history.
- Review of current medications and over the counter products you are taking.
- Complete pelvic examination, including pap smear, assessment of vaginal maturation index and vaginal pH, pelvic organ prolapse evaluation, and visual assessment of vaginal dryness.

Treatment Visits (Weeks 1, 5, 9)

If you are eligible to participate in the study, you will have laser treatments inside your vagina every 4 weeks for a total of up to 3 treatments over 8 weeks (2 months).

The laser treatment procedure is performed by using a fractional handpiece (a specially designed handpiece with an angled mirror) that is designed specifically for use in the vagina. It is attached to the Perigee Medical Edge CO2 laser, which delivers laser energy through a special lens that divides the energy into the vaginal tissue to stimulate collagen growth and activation of fibroblasts. Each laser treatment should take about 10 to 15 minutes to complete. See Figure 1 below.

A laser treatment procedure is performed as follows:

1. An instrument called a speculum will be placed into your vagina. The speculum holds the walls of the vagina apart and allows a clear view of the vaginal canal and cervix.
2. The study doctor will exam the vaginal tissue and gently cleanse the area to be treated using a sterile cotton swab or gauze sponge to remove any excessive mucus in the treatment area.
3. The fractional handpiece and a scope are placed through the speculum into the vagina to deliver laser energy along the vaginal canal.
4. The handpiece is positioned to the end of the vaginal canal and gently pulled back at one centimeter intervals as it delivers triggering laser pulses until the handpiece reaches the entrance of the vagina. This motion is repeated up to 3 times.
5. Once the laser process described above is complete, the handpiece, scope, and speculum are removed from the vagina.

The study doctor will discuss with you the post-procedure instructions, such as not inserting anything in your vagina for 7 days and avoiding all estrogen therapy medications. You will be provided with Lidocaine Ointment 5% to apply to the outside of the vagina every 4 hours as needed for the next 1-2 days.

For treatment visits 2 and 3, the study doctor will ask whether you are experiencing any side effects, discuss any changes in your medical history and will review any medications and over the counter products you are taking.

Figure 1:

Follow-Up Period (Weeks 2, 6, 10, 43)

After each laser treatment procedure, you will come back to the clinic the following week for a pelvic examination to examine the treatment area. You will also complete a series of standardized surveys that ask questions about topics related to your condition, such as pelvic organ prolapse, sexual function and urinary incontinence.

You will return back to the clinic about 8 months after your final treatment and have a pelvic exam to examine the treatment area. At that visit the study doctor, will evaluate you for signs and symptoms of VVA.

RISKS AND DISCOMFORTS
You will be followed closely by the study doctor for the entire time you are a part of this study. **If you experience any side effects, contact the study doctor, Dr. Sherry Thomas.** The study doctor will provide you with the treatments that have the best chance of taking care of them. This study may include risks that are unknown at this time.

Your condition may not get better or it may get worse during this study. You will be followed by the study doctor for the entire time you are a part of this study. If you experience any side effects, you will be provided with the treatments that have the best chance of taking care of them.

CO2 Laser Risks: You may feel a heating sensation or some pain during or following the treatment. Other side effects may include:

- mild burns in the vaginal canal
- chronic urinary tract infections
- vaginal infections
- moderate to severe vaginal bleeding (more than a menstrual period)

If you experience severe irritation, vaginal bleeding, pain, discomfort, or infection, your laser treatments will be stopped. You can also discontinue any laser session if you are not able to tolerate the discomfort that may occur during the treatment.

Risks of Lidocaine: Most common risks for lidocaine include burning at administration site, skin inflammation, erythema (skin redness) and itching.

Potential Drug Interaction Risks: There is the potential that the current medications you are taking may cause problems with the laser treatment procedures. The study doctor will carefully review all the medications you are taking before each laser treatment. If any other health care provider prescribes any new drug(s) for you while you are in this study, please tell the study doctor. Do not take any new over-the-counter drugs while you are in this study unless you first check with the study doctor.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS
If you agree to participate in this study, your condition may improve while you are in this study; however, this cannot be promised. The results of this study may help people with vulvovaginal atrophy or similar conditions in the future.

COSTS
All tests performed solely for the research will be provided free of charge during this study. You or your insurance company may be billed for all standard medical care given during this research study. Please ask the study doctor to explain which tests are required for your standard medical care and which tests are being performed solely for the purposes of this research.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor.

You will not be paid for your participation in this research study.

ALTERNATIVE TREATMENT
You may wish to talk with your treating physician about your choices before deciding if you will take part in this study. You do not need to be in this study to receive treatment for vulvovaginal atrophy. If you decide not to enter this study, there are other choices available. These include:

- Receiving no treatment at this time.
- Use of herbs, lubricants, and hormonal treatments (e.g., estrogen).
- Taking part in another study (if available).

CONFIDENTIALITY OF INFORMATION COLLECTED FOR RESEARCH PURPOSES
We will take steps to keep your personal information private, but we cannot guarantee total confidentiality. All identifiable information about you will be replaced with an alphanumeric code. A list linking the code and your identifiable information will be kept separate from the research data. All research data and records will be stored in a locked cabinet or electronically on a secure network with encryption and password protection to help prevent unauthorized access to your personal information. We will not release information about you to others not listed below, in the AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES, unless required or permitted by law. We will not use your name or your identity for publication purposes, unless we have your special permission. Your research data and records may be kept indefinitely by the study Investigator.

COMPENSATION FOR INJURY
If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. If you decide to stop being in this study, contact the study doctor. Your decision not to participate or to leave the study at any time will not result in any penalty or loss of benefits to which you are entitled.

Information that has already been collected before the date of withdrawal will still be used to make the research reliable. No additional information will be obtained.

Your participation in this study may be stopped at any time by the study Investigator or the sponsors without your consent for any reason, including:

- If it is in your best interest (e.g., your welfare is at risk);
- Subject enrollment is unsatisfactory;
- Subject enrollment is complete;
- Data recording is inaccurate or incomplete.

If you leave the study before the planned final visit, you will be asked by the study doctor to come to the clinic for a one-month follow-up visit so that you leave the study safely.

SOURCE OF FUNDING FOR THE STUDY
The Sponsor, Perigee Medical, will pay for this research study.

WHO TO CONTACT FOR QUESTIONS
Contact **Dr. Sherry Thomas** from the study team at (818) 480-7100 (24 Hours) for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury, and/or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and feel you have received satisfactory answers. If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

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.

CONSENT STATEMENT

I have read this consent form (or it has been read to me). All of my questions about the study, and my part in it, have been answered. I freely consent to participating in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name (printed)

CONSENT SIGNATURE:

_____	_____
Signature of the Subject (18 years and older)	Date
_____	_____
Printed Name of Person Conducting the Informed Consent Discussion	Position
_____	_____
Signature of Person Conducting the Informed Consent Discussion	Date

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past, present, and future medical records.
- Research records created for the study.
- Records about phone calls and emails made as part of this research.
- Records about your participation in clinical trials.

Who may use and give out information about you?
The study doctor and the study staff.

Who might get this information?
The sponsor of this research, Perigee Medical. “Sponsor” means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Western Institutional Review Board® (WIRB®).

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

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

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.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2060.

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 study doctor. 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.

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.

_____
Subject Name (printed)

CONSENT SIGNATURE:

_____ _____
Signature of the Subject (18 years and older) Date

_____ _____
Printed Name of Person Conducting the Informed Consent Discussion Position

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date