

Information for Postmenopausal Women with Sexual Pain Interested in the Clinical Trial

GTO Pharmaceutical, LLC

The Purpose of the Clinical Trial:

We are testing the effectiveness of a non-hormonal, topical, botanical drug for vulvar sexual pain in postmenopausal women.

Who is this for?

- ▶ Postmenopausal women experiencing pain in the area surrounding the opening of their vagina only when this area is touched, pressed upon or rubbed
- ▶ This pain must be present for at least 3 months in duration



What is the topical study drug being tested in this Clinical Trial?

- ▶ 15% sincatechins is an FDA approved topical botanical drug made from green tea. It has been used by both women and men for the past 14 years.
- ▶ The investigational drug being tested in this clinical trial is 10 % sincatechins. It is a lower concentration of the FDA approved topical botanical drug.
- ▶ **Throughout the history of medicine, it is common for an approved drug used, for many years for one purpose, to be investigated for its effectiveness for an entirely different condition.

What is the purpose of this Clinical Trial?

- ▶ The purpose of this clinical trial is to test the effectiveness of **10% sinecatechins** for provoked vulvar vestibular pain in postmenopausal women.
- ▶ **Provoked vulvar vestibular pain** is pain experienced when the area directly outside of the opening to the vagina is touched, pressed upon or rubbed.

What is expected of me if I qualify?

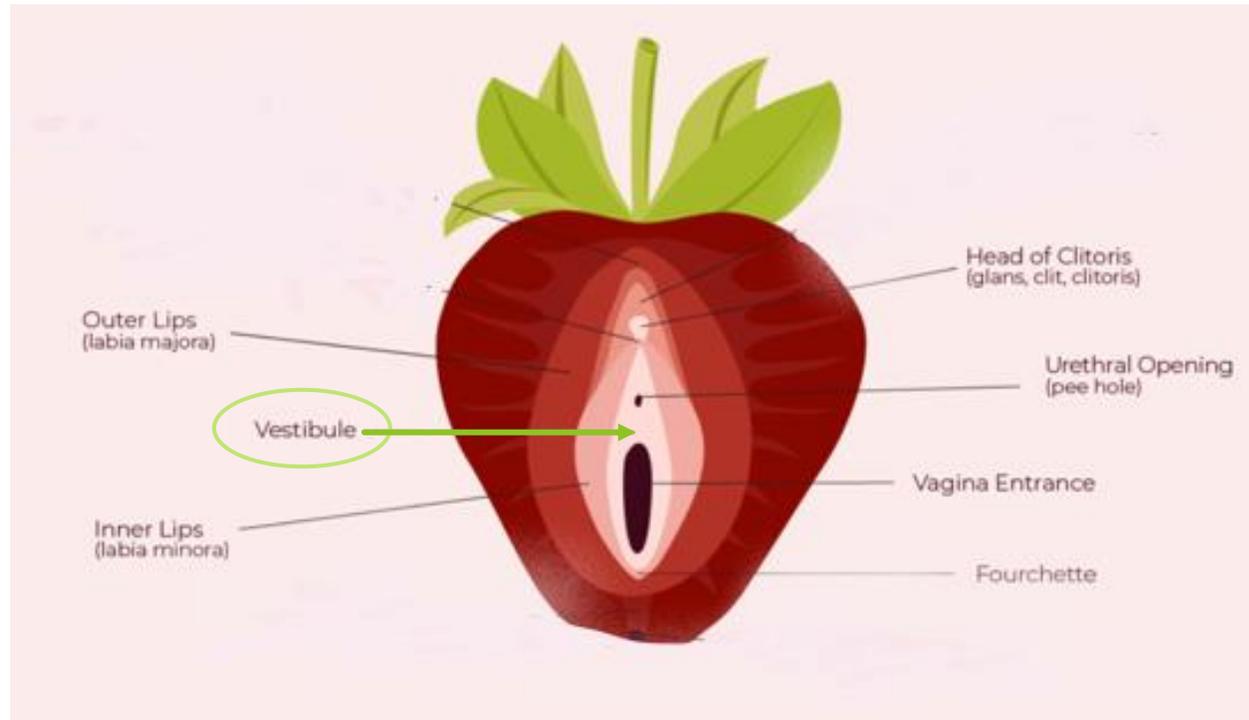
- ▶ **3 in-office visits to the gynecologist over the month**
 - Investigators include board certified gynecologists on faculty at NYU and Mount Sinai
 - Gynecology offices are located in New York City and Rockland County, New York
- ▶ **Applying either the topical 10% sinecatechins botanical investigational drug or placebo**
- ▶ **Filling out questionnaires throughout the course of the study onsite during each in-office visit and online at the end of each week between visits**

Why Participate?

- ▶ Compensation for your time and travel (up to \$200 for completion of all three visits, questionnaires both in office and online)
- ▶ Study-related care, at no charge, from a local gynecologist in N.Y.C. or Rockland County, NY
- ▶ The topical investigational drug, at no charge, (10% sinecatechins ointment or placebo)
- ▶ You may benefit in the following ways:
 - Decrease in sexual pain
 - Increase in lubrication
 - Increase in sexual arousal
 - Increase in orgasmic intensity

Where must my pain be in order to qualify?

- ▶ You must be experiencing pain in your Vulvar VESTIBULE (the lightest pink area just outside of the vaginal entrance)



The **Vestibule** is located between Hart's Line and the vaginal opening

Hart's Line

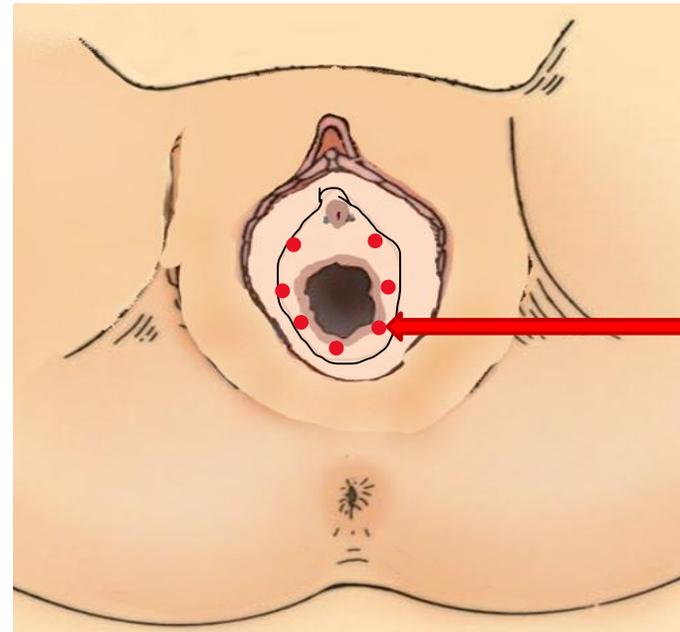
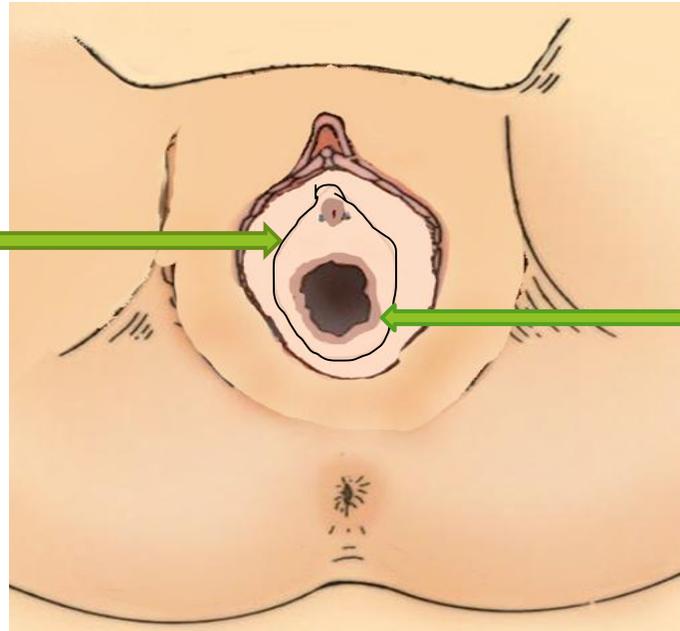


Vestibule



The source of pain must be located in the Vulvar Vestibule

Vestibular Pain



What other types of sexual pain would **exclude me from participating?**

- ▶ **Vaginal Pain:** Pain experienced only on the inside of the vagina
- ▶ **Muscle Pain:** Pain from Pelvic Muscle Floor Muscle Spasms
- ▶ **A Tight or Constricted or Rigid Hymenal Ring:** Pain due to loss of elasticity, narrowing and constriction of the Hymenal ring
- ▶ **Spontaneous or unprovoked vulvar vestibular pain:** Pain in the vulvar vestibule that is experienced without touching, rubbing or pressing on the area (unprovoked vulvar vestibular pain)

Vaginal Pain

- ▶ **Vaginal Pain:** Pain experienced only on the inside of the vagina
- ▶ **If you only are experiencing pain on the inside of your vagina or if your main source of pain is from inside your vagina but NOT on the area surrounding the opening to the vagina you would not be eligible to participate in the clinical trial. Please consult your personal gynecologic healthcare professional for alternative treatment.**

Muscle Pain

- ▶ **Muscle Pain:** Pain from Pelvic Muscle Floor Muscle Spasms
- ▶ Some women experience spasms or tightening or contractions of the muscles that make up the pelvic floor. These contractions can be very intense and painful and even preclude any vaginal penetration.
- ▶ **IF this is the source of your pain, then you would not be eligible to participate in this clinical trial.** However, there are alternative treatments and specialists that may help you so please discuss this with your personal gynecologic healthcare professional.

What else might
be the cause of
my pain on the
outside of my
vagina?

Pain from a Tight, Constricted or Rigid opening at the entrance to the vagina

- ▶ **A Tight or Constricted or Rigid Ring** directly at the opening to the vagina can be a source of extreme pain. One may experience pain upon insertion of even a finger into the opening of the vagina because the opening is narrow, tight and/or firm.
- ▶ **If this is the main source of your pain, then you would not be eligible to participate in this clinical trial.** There maybe alternative treatment options. Please consult with your personal gynecologic healthcare professional.

Unprovoked Vulvar Vestibular Pain

- ▶ **Unprovoked Vulvar Vestibular Pain:** Some women experience pain spontaneously, unprovoked, e.g.: **without** any touching, rubbing or pressing on the area surrounding the opening to the vagina.
- ▶ **If you feel pain in your vulvar area without any touching, rubbing or pressing then you would not be eligible to participate in this clinical trial.** There maybe alternative treatment options. Please consult with your personal gynecologic healthcare professional.

For postmenopausal women with Provoked Vulvar Vestibular Pain

- ▶ If the pain that you have been experiencing
 - ▶ 1. has been present for at least 3 months **and**
 - ▶ 2. occurs from touching, pressing upon, rubbing or manipulating the area surrounding the opening of your vagina **and**
 - ▶ 3. you would describe that pain as significant to severe **then you may qualify to participate in this clinical trial.**

How do I find out if I qualify for the trial?

WEBSITE

Your may visit gtopharmaceutical.com and fill out the contact form

EMAIL

Or your may email Annamarie DeRosa, the Clinical Trial Coordinator at clinicaltrialpa@gmail.com for the next steps in learning how to participate in the clinical trial for postmenopausal women with provoked vulvar vestibular pain.