Clinical Study of a Vaginal Cooling Device for the Treatment of Vulvo-vaginal Candidiasis (VVC)

NCT06983041

Status	RECRUITING
Phase	Not Applicable
Sponsor	Coologics, Inc
Enrollment	55 participants

Key Eligibility Criteria

Inclusion (10)

- Women between 22-49 years of age and not more than one year since last menses, with the suspected diagnosis of uncomplicated VVC.
- Able to read and understand English.
- Able to provide written informed consent and to understand and agree to all study procedures required.
- Has a smart phone and has the ability to access and use the ValidCare app.
- Documented Papanicolaou (Pap) test at baseline or during the previous 12 months reported as either "negative for intraepithelial lesion or malignancy" or "ASCUS-atypical squamous cells of undetermined significance" and negative for high-risk HPV types or negative colposcopy plus/minus biopsies were performed for high-risk HPV types.

... and 5 more (see full listing online)

Exclusion (6)

- \. Subject does not have a smart phone. 3. Subject does not have the ability to access and use the Validcare app. 4. Subjects who were treated for VVC within the past 14 days. 5. Use of systemic, topical (applied to the vulva) or vaginal antibiotics, anti-fungal or anti-trichomonas drugs within 14 days.
- \. Use of any systemic corticosteroid, immunosuppressive, or immune-stimulating drug within 3 months.
- \. History of douching within the previous 7 days. 8. Urinary tract infection. 9. Unable or unwillingness to use tampons in the past. 10. Unable to maintain study protocol including but not limited to the avoidance of sexual activity during the 28 days or time interval up to the assessment of the primary endpoint. This is needed to avoid reinfection, worsening of symptoms or new pathogen infection, while assessing the efficacy of the subject device in treating the primary infection.
- \. Use of anticoagulation therapy (e.g., warfarin, heparin). 12. Diabetes mellitus. 13. History of vulvodynia, vestibulitis, vaginismus, radiation-induced vaginitis, or postmenopausal atrophy.
- \. Immune compromised states such as HIV/AIDS or transplant subjects. 15. Subjects with other infectious causes of vulvo-vaginitis or with mixed infections diagnosed at baseline. (Note: if any trichomonad trophozoites are seen on wet smear on the initial visit, the subject is to be excluded from the study.) 16. Symptomatic vulvar or vaginal condyloma or presence of another vaginal or vulvar condition that would confound the interpretation of clinical response.

... and 1 more (see full listing online)

Locations (10 total)

Symphony Clinical Research, Jacksonville, Florida, United States
Nova Clinical Research, Miami, Florida, United States
Pivotal Clinical Research & Associates, Smyrna, Georgia, United States
... and 7 more locations