

Safety and Efficacy of Boric Acid Inserts for Treatment of Vulvovaginal Candidiasis

NCT07109869

Status	RECRUITING
Phase	Phase 3
Sponsor	pH-D Feminine Health LLC
Enrollment	400 participants

Key Eligibility Criteria

Inclusion (23)

- Patients who are postmenarcheal, nonpregnant biological females, 12 years of age and older, at Screening;
- Patients with acute symptomatic VVC infection at Screening, defined as meeting all of the following criteria:
 - A potassium hydroxide (KOH) wet mount or saline wet mount preparation performed from the inflamed vaginal mucosa or secretions demonstrating yeast forms (hyphae or pseudohyphae) of or budding yeast;
 - Vaginal pH ≥ 4.5 ; and
 - Total Vulvar Signs and Symptoms (VSS) Scale score of ≥ 4 : vulvovaginal signs (edema, erythema, and excoriation/fissures) and symptoms (vulvovaginal burning, itching, and irritation) as rated using the VSS Scale.

... and 18 more (see full listing online)

Exclusion (31)

- Patients with known or suspected other active infectious causes of cervicitis, vaginitis, or vulvitis (eg, BV, Chlamydia trachomatis, Neisseria gonorrhoeae, T. vaginalis, or genital lesions consistent with HPV, herpes simplex, syphilis, chancroid, etc) based on the results of clinical assessments, in-clinic microscopic assessments (eg, clue cells or trichomonads detected on saline wet mount), and/or rapid diagnostic tests (RDTs) performed prior to enrollment (eg, OSOM® test, etc);
- Patients who have undergone any vaginal rejuvenation procedure (ie, laser) within 4 weeks prior to Screening or plan to undergo a vaginal rejuvenation procedure prior to completion of the last planned assessment;
- Patients who will undergo evaluation or treatment during the clinical study for abnormal cytology or findings from high-risk HPV testing or Pap test finding;
- Patients diagnosed with BV, determined by meeting 3 of the 4 Amsel's criteria:
- A fishy odor of the vaginal discharge before or after the addition of a drop of 10% KOH (ie, a positive whiff test);

... and 26 more (see full listing online)

Locations (27 total)

Alliance for Multispecialty Research - Mobile, Mobile, Alabama, United States
Abby's Research Institute, Phoenix, Arizona, United States
Applied Research Center of Arkansas Inc., Little Rock, Arkansas, United States
... and 24 more locations

<https://clinicaltrials.gov/study/NCT07109869>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.