An Investigation to Evaluate the Clinical Performance and Safety of pHyph in Adult Women With Vulvovaginal Candidiasis Compared With an Untreated Control Group

NCT07405853

Status	RECRUITING
Phase	Not Applicable
Sponsor	Gedea Biotech AB
Enrollment	48 participants

Key Eligibility Criteria

Inclusion (10)

- Willing and able to give written informed consent for participation in the clinical investigation, and to comply with all clinical investigation requirements.
- Adult, post-menarchal, pre-menopausal women aged 18 years or older.
- Diagnosis of VVC, defined as:
- Having a white or creamy vaginal discharge, and
- at least two signs (erythema, oedema and excoriation) and/or symptoms (itching, burning irritation) of VVC scored as at least 2 = moderate on a scale of 0-3, and

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

Exclusion (11)

- Patients with known or apparent signs of other infectious causes of vaginal infection and/or vaginitis (e.g., BV, Trichomonas vaginalis, Neisseria gonorrhoeae, Chlamydia trachomatis, herpes simplex virus or human papillomavirus) at screening.
- History of or presence at screening (Day 0) of any other clinically significant disease or disorder, medical/surgical procedure, or trauma, which, in the opinion of the Investigator, may either put the patient at risk because of participation in the clinical investigation, or influence the results or the patient's ability to participate in the clinical investigation.
- Anticipated menstruation during the first treatment period (Day 0 until Day 7). If a patient is menstruating on Day 0, or if menstruation is anticipated during Days 0 to 7, inclusion can be postponed to an additional visit at a later date when the menstrual bleeding is no longer heavy (light bleeding or brown discharge is acceptable).
- Patients who are pregnant or breastfeeding.
- Patients who are planning to conceive within the 25 days of the investigation.

... and 6 more (see full listing online)

Locations (3 total)

CTC, Ebbe Park, Linköping, Sweden
CTC Stockholm, Solna, Sweden
CTC, Uppsala, Sweden