A Study of the Efficacy and Safety of WXSH0102 in Treating VCC Patients

NCT06771063

Status	RECRUITING
Phase	Phase 2
Sponsor	Cisen Pharmaceutical CO., LTD.
Enrollment	108 participants

Key Eligibility Criteria

Inclusion (5)

- The subjects understood and voluntarily signed the informed consent Form (ICF), and were willing and able to comply with the study protocol.
- Female participants who signed ICF at the age of 18-64 years (including the cut-off value) and had sexual intercourse;
- Participants were diagnosed with VVC and met each of the following criteria: a. At screening, the total score on the VVC scale was e4 and at least two of the symptoms or signs on the VVC scale were present; b. A vaginal discharge sample collected at screening was Gram stain positive for Candida (hypha/pseudohypha/budding); c. Vaginal pH d4.5; Symptoms: vulvovaginal itching, vulvar burning pain, dyspareunia and urination pain, excessive secretion, secretion is tofu residue like; Physical signs: gynecological examination showed vulvar hyperemia and edema, which may be accompanied by scratches. In severe cases, chapped skin, exfoliation and even erosion could be seen. Vaginal mucosa was hyperemic, vaginal secretion was curd or tofu residue like;
- Subjects who are capable of oral administration;
- For the duration of the study, participants agreed to abstain from sexual activity and to use the condom throughout sexual activity.

Exclusion (7)

- Known or suspected allergic history to any component of this product, fluconazole or pyrrole drugs;
- Subjects with any vulvovaginal or cervical disease that may affect the diagnosis and evaluation of VVC;
- Topical or systemic antifungal treatment for VVC within 14 days before randomization;
- Significant liver disease or abnormal liver function tests (alanine aminotransferase \[ALT\], aspartate aminotransferase \[AST\] \> 1.5 ULN); Patients with severe renal disease or renal insufficiency (glomerular filtration rate (GFR) \< 60ml/min/1.73m2);
- Patients who planned to undergo treatment or surgery for vulvar, vaginal or cervical lesions during the study period;

... and 2 more (see full listing online)

Locations (2 total)

251 Yaojiayuan Road, Chaoyang District, Beijing, Beijing, Beijing Municipality, China
Beijing Obstetrics and Gynecology Hospital, Beijing, Beijing Municipality, China