Safety and Efficacy Study of VNX001 Compared to Its Individual Components (Lidocaine and Heparin) or Placebo in Subjects With IC/BPS

NCT05737121

Status	RECRUITING
Phase	Phase 2
Sponsor	Vaneltix Pharma, Inc.
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (6)

- Be able and willing to give a signed informed consent and to follow study instructions
- Be male or female, e 18 years of age
- Have a history of IC/BPS for at least 9 months prior to the study
- Have a score of e 16 and d 30 on the Pelvic Pain and Urgency/Frequency (PUF) questionnaire, completed at screening
- Have an episode of acute bladder pain of moderate to severe intensity with a minimum score of 5 on the 11-point bladder pain NRS at time of screening and 15 minutes post void immediately prior to study drug administration.

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

Exclusion (39)

- For females, have a positive pregnancy test at screening or be pregnant or lactating
- Males who are sexually active with females and are not willing to commit to an acceptable method of birth control for the duration of the
- Postmenopausal women who, if taking hormone replacement therapy, have not been stabilized on a regimen of hormone replacement therapy within 3 months of screening
- Have a known hypersensitivity to heparin or lidocaine
- Have used any local anesthetic by any route within 48-hours prior to study drug administration, or used a lidocaine patch or lidocaine containing topical compounds within 14 days prior to study drug administration

... and 34 more (see full listing online)

Locations (14 total)

IC Study LLC, Escondido, California, United States
University of California Los Angeles Center for Women's Pelvic Health, Los Angeles, California, United States
The Clark Center for Urogynecology, Newport Beach, California, United States
... and 11 more locations