# Vestibulectomy Surgical Techniques Comparison Study

NCT05343182

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| **Status** | RECRUITING |
| **Phase** | Not Applicable |
| **Sponsor** | Oregon Health and Science University |
| **Enrollment** | 118 participants |

## Key Eligibility Criteria

### Inclusion (5)

- Reported provoked tenderness to the vestibule for at least 3 months in non-pregnant, estrogen-replete healthy subjects aged 18 years or over meeting Friedrich's criteria for PVD44-45 and supported by the ISSVD Terminology Consensus Definition45 for vulvar pain. Subjects who are \>45years of age must have either have a maturation index52 of \< 10% parabasal cells or willingness to participate in local estrogen replacement until achieving this same clinical result.
- Cotton swab Test30-31 mean verbal rating score of e4/10 in 4 of 6 defined points of the vestibule (2, 4, 6, 8, 10, 12 o'clock) and cotton swab test verbal score d 2/10 for the labia majora and minora, intra labial sulcus, and perineum
- Ability to insert a regular Tampax® tampon
- Baseline Tampon Test verbal pain score e430
- f. Phone and internet access e. Willingness to engage in pelvic floor physical therapy (PT)

### Exclusion (5)

- Pregnancy
- Any other clinical reason for dyspareunia (endometriosis pain, chronic pelvic pain, vulvar dermatoses such as psoriasis, lichen sclerosus)
- Unable or unwilling to complete baseline assessments
- Prior vestibulectomy or hymen surgery
- Prior or current use of testosterone dosed for gender affirmation

## Locations (1 total)

Oregon Health and Science University, Portland, Oregon, United States