

Changes in the Impact of Genitourinary Syndrome of Menopause With a Novel Nonhormonal Vulvovaginal Gel Assessed by PROMs.

NCT06962345

Status	RECRUITING
Phase	Not Applicable
Sponsor	Mucosa Innovations, S.L.
Enrollment	80 participants

Key Eligibility Criteria

Inclusion (5)

- Patient has to have at least one symptom of GSM or suffer from symptoms related to vulvovaginal atrophy (as evidenced by gynecological examination with a Vaginal Health Index d15).
- Patient must be postmenopausal with at least 1 year without a menstrual period.
- Patient must consider that her quality of life is affected by GSM symptoms
- Patient not followed due to any gynecological disease.
- All participants must be able to understand and to fill in the self-reported questionnaires.

Exclusion (13)

- Patients that do not want to fill the questionnaire, especially the questions that address sexual functioning.
- Participants that use any oral products containing hormones or estrogen receptor modulators for the past 8 weeks, nor vaginal topical hormone products within 4 weeks, neither prescription nor non-prescription therapies for GSM, including topical vaginal non-hormonal lubricants or moisturizers for the last week.
- Patients with history of vulvar, vaginal and/or cervical malignancy.
- Patients having received radiotherapy treatment in the pelvic and/or genital region.
- Patients with any type of disease that causes alteration of collagenogenesis.

... and 8 more (see full listing online)

Locations (1 total)

Mucosa Innovations S.L., Madrid, Madrid, Spain