# Pragmatic Evaluation of Performance and Safety of the Anchorsure® Transvaginal Device for Surgical Treatment of Apical Prolapse in Women

NCT05836844

**Status** RECRUITING
**Sponsor** Centre Hospitalier Universitaire de N+mes
**Enrollment** 120 participants

## Key Eligibility Criteria

### Inclusion (4)

- Women with pelvic organ prolapse with leading edge at or beyond the hymen as confirmed by the pelvic organ prolapse quantification system (POP-Q), i.e. Ba e -1 cm for the anterior compartment, and/or Bp e -1 cm for the posterior compartment, and/or C e -1 cm for the apical compartment including recurrence.
- Women due for POP surgery using the Anchorsure System® for apical prolapse suspension with or without concomitant native tissue repair, with or without concomitant hysterectomy and with or without concomitant sling for stress urinary incontinence.
- All women who have not indicated any objection to participating in the study.
- All women who have been correctly informed.

### Exclusion (10)

- Patient taking part or having taken part in a device or drug interventional study within the last three months (except for VIGI-MESH national registry).
- Patients due for pelvic organ prolapse repair without apical suspension or with anything other than native tissue repair and the Anchorsure System®.
- Patients with uncontrolled diabetes mellitus.
- Patients with active non-controlled or chronic gynaecologic or urinary tract infection and/or local tissue necrosis.
- Patients with ongoing pelvic organ cancer (e.g. uterine, ovarian, bladder, cervix …).

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

## Locations (4 total)

La Rochelle General Hospital, La Rochelle, France
Lille University Hospital, Lille, France
Kremlin-Bicêtre Hospital, Paris, France
... and 1 more locations