

# Randomized Study Evaluating the Treatment of Vulvovaginal Gaping by Plication of the Puborectalis Muscles Versus Perineorrhaphy ± Transverse Myorrhaphy of the Puborectalis Muscles at 12 Months. (HERA)

NCT07245823

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Ramsay Générale de Santé
Enrollment	100 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Female patient between 18 and 80 years-old.
  - Genital hiatus at rest  $\leq$  4 cm by POP-Q
  - Sexually active woman without pain (never/rarely scored) during penetration and who has stopped sexual activity due to vulvovaginal incompetence without pain (never/rarely scored) during penetration
  - Prolapse
  - Candidate for surgery for anatomical reconstruction of the vulvovaginal incompetence
- ... and 2 more (see full listing online)

### Exclusion (10)

- Resting GH  $\geq$  4 cm (POP-Q classification)
  - Women not sexually active and not planning to become sexually active
  - Chronic perineal pain syndrome
  - Anal sphincter injury with concomitant indication for sphincterorrhaphy
  - Cognitive or language impairment of the patient unable to complete the study questionnaires
- ... and 5 more (see full listing online)

## Locations (1 total)

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Hopital privé Dijon Bourgogne, Dijon, France