

Single-incision Versus Retropubic Mid-Urethral Sling (Solyx) for SUI During Minimally Invasive Sacrocolpopexy

NCT04586166

Status	RECRUITING
Phase	Not Applicable
Sponsor	Wake Forest University Health Sciences
Enrollment	180 participants

Key Eligibility Criteria

Inclusion (7)

- At least 21 years of age
 - Vaginal bulge symptoms as indicated by an affirmative response of ≥ 1 to question 3 of the PFDI-SF20
 - POP e stage II according to the pelvic organ prolapse quantification (POP-Q) system⁴⁵, with evidence of apical descent
 - Women being considered for minimally invasive sacrocolpopexy (with or without concomitant hysterectomy)
 - Objective SUI: positive standardized cough stress test on clinical examination or on urodynamic study with reduced prolapse
- ... and 2 more (see full listing online)

Exclusion (13)

- Prior surgery for stress urinary incontinence including mid-urethral sling; Burch/MMK; fascial pubovaginal sling (autologous, xenograft or allograft); and urethral bulking injection
 - Any serious disease, or chronic condition, that could interfere with the study compliance
 - Unwilling to have a synthetic sling
 - Untreated and unresolved urinary tract infection
 - Poorly-controlled diabetes mellitus (HgbA1c ≥ 9 within 3 months of surgery date)
- ... and 8 more (see full listing online)

Locations (7 total)

Augusta University, Augusta, Georgia, United States
Northwestern Medicine, Chicago, Illinois, United States
University of Chicago, Chicago, Illinois, United States
... and 4 more locations