

Trial of Transurethral Bulking Agent Injection Versus Single-Incision Sling for Stress Urinary Incontinence

NCT06480227

Status	RECRUITING
Phase	Not Applicable
Sponsor	NICHD Pelvic Floor Disorders Network
Enrollment	358 participants

Key Eligibility Criteria

Inclusion (7)

- Women ≥ 21 years
 - Bothering SUI (PFDI-20 Q:#17 of somewhat, moderately or quite a bit) or stress predominant MUI (PFDI-20 Q:#16 < Q:#17) 50% or more of the time for > 3 months with well-controlled UII on stable medication treatment through baseline and follow-up.
 - A positive cough stress test or urodynamic SUI within the past 18 months.
 - Normal voiding function as demonstrated by PVR < 150 mL
 - Candidate for either study procedure as determined by treating surgeon (i.e., failed or unable to perform conservative management for SUI including pelvic floor strengthening and failed or declines pessary option for SUI)
- ... and 2 more (see full listing online)

Exclusion (12)

- Anterior/apical vaginal prolapse beyond the hymen (>0 on POPQ) - Advanced prolapse may require additional surgery or potentially increase the risk of postoperative urinary obstruction and confound the results of the study.
 - Urge-predominant mixed UI by UDI-6 despite stable therapy - Urge predominant UI would not be expected to improve after TBA or SIS and may bias results of interventions designed specifically for stress urinary incontinence.
 - Planned hysterectomy, urethral or anterior/apical surgeries - additional surgery beyond TBA or SIS has potential to confound the results. Additionally, these procedures generally require general anesthesia and indwelling catheterization immediately post operatively. The impact of urethral instrumentation after TBA is unknown and could impact the efficacy of the urethral coaptation.
 - Malignancy or history of radiation of the pelvis - The risk of foreign material rejection and mesh complications may be higher in women with pelvic radiation and other treatment for pelvic malignancy may impact primary outcomes.
 - Pregnant, breast feeding or plans for pregnancy within 1 year - subsequent vaginal delivery and hormonal changes of breast feeding prior to primary outcome could impact the efficacy of either treatment.
- ... and 7 more (see full listing online)

Locations (7 total)

University of California at San Diego, La Jolla, California, United States
Kaiser Permanente -- San Diego, San Diego, California, United States
University of Chicago, Chicago, Illinois, United States
... and 4 more locations

<https://clinicaltrials.gov/study/NCT06480227>

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