

Safety and Feasibility Study of Autologous Engineered Urethral Constructs for the Treatment of Strictures

NCT03258658

Status	RECRUITING
Phase	Phase 1
Sponsor	Wake Forest University Health Sciences
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (4)

- Stricture of the urethra meeting the following criteria:
- a) History of at least one 15-60 mm in length, as determined by urethrography. c) Contains at least 1 strictured segment through which a 16 Fr flexible cystoscope cannot be atraumatically passed.
- Patients must be available for all follow-up visits.
- Ability to speak English.

Exclusion (25)

- Strictures of the meatus or prostatic urethra; any urethral stricture associated with or suspected to be urethral carcinoma, or strictures due to pelvic distraction injuries. Strictures ≤ 10 mm or ≥ 60 mm, as determined by urethrography, and criteria for bulbar urethral strictures excluding those with strictures ≤ 20 mm and ≥ 60 mm, as described by urethrography.
- Presence of untreated urinary tract infection.
- Presence or prior history of lichen sclerosus et atrophicus (previously termed 'balanitis xerotica obliterans').
- Uncontrolled bleeding disorder or patients with a platelet count less than 50,000, hemophilia or patients routinely receiving blood products for bleeding disorders.
- Any urological condition that would be likely to require additional urethral instrumentation during the period of investigation, including, but not limited to benign prostatic hyperplasia requiring treatment, use of alpha blockers, active prostate cancer, an unevaluated elevated prostate surface antigen (PSA), bladder cancer, or any recurrent urinary stone formation. Patients with evidence or diagnosis of any coagulation disorder (including concomitant anti-coagulation therapy at enrollment).

... and 20 more (see full listing online)

Locations (2 total)

University of California San Francisco, San Francisco, California, United States
Wake Forest Institute for Regenerative Medicine (WFIRM), Winston-Salem, North Carolina, United States