

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Evaluation of the surgical result of urethroplasty by vaginal wall flap in female urethral stricture in a pilot study

#### Protocol summary

##### Study aim

The purpose of this study was to evaluate the results of urethroplasty surgery using vaginal wall flap in the treatment of urethral stenosis in women. Determining the frequency of symptom recurrence - fistul formation - urinary incontinence - Recurrence of stenosis - Normal urination and reduction of pvr in urethroplasty using vaginal flap in the treatment of urethral stricture

##### Design

The study is performed on 10-15 patients with urethra stricture because there are no other methods for performing this type of surgery in Iran. It is not possible to compare this.

##### Settings and conduct

Patients with urethral stenosis referring to Imam Reza Hospital in Tabriz in the years 1396-97 (first 97 months), . -patients undergo urethroplasty surgery using vaginal flap. Patients will receive follow up 3-6 months later, then they will be provided with Eurodynamic . Concerning removal and reduction of obstructive urethral symptoms according to the AUA Symptom Score questionnaire, reduction of PVR and QMAX recovery, as well as recurrence of symptoms and complications to be evaluated

##### Participants/Inclusion and exclusion criteria

Entry: Female patients with urinary tract stenosis aged over 18 years who did not respond to conservative, drugs, and dilatation, or did not have an informed consent to do the above measures and had an excess of pvr of 100 Exit: skin problems such as lichen planus or immunosuppression, or virgin subjects or not the informed consent of the above surgery , neurogenic bladder disorders in the urodynamics

##### Intervention groups

10 to 15 patients with urethral stricture undergo urethroplasty surgery using vaginal flap.

##### Main outcome variables

-symptom recurrence- -urinary incontinence- - fistula- -

Stenosis recurrence - -normal urination-- reduction of pvr{post voiding residury}

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130306012728N5**

Registration date: **2018-06-02, 1397/03/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-02, 1397/03/12**

Update count: **0**

##### Registration date

2018-06-02, 1397/03/12

##### Registrant information

##### Name

Sakineh Hajebrahimi

##### Name of organization / entity

Urology Department, Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7328

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-21, 1396/01/01

##### Expected recruitment end date

2018-06-21, 1397/03/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the surgical result of urethroplasty by vaginal wall flap in female urethral stricture in a pilot study

**Public title**

Evaluation of the surgical result of urethroplasty by vaginal wall flap in female urethral stricture in a pilot study

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with urinary tract stricture aged over 18 years who had stricture of the urethra and did not respond to conservative, drug and dilatation treatments, or did not have an informed consent to the above measures, and had a higher than 100 cc pvr , if satisfied with orthoplasty Using the vaginal flap

**Exclusion criteria:**

Patients with skin problems such as Lichen planus or Immunosupercise, or virginal patients, not the deliberate consent of the above surgery [after the description], or those who have had neurogenic bladder in the eurordynamics , are excluded from the action list.

**Age**

From **18 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **10**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee**

**Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences, Attar Neyshabouri Street, Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

+41 33347054

**Approval date**

2018-04-30, 1397/02/10

**Ethics committee reference number**

IR.TBZMED.REC.1397.110

**Health conditions studied****1****Description of health condition studied**

female urethral stricture

**ICD-10 code**

N35.8

**ICD-10 code description**

Other urethral stricture

**Primary outcomes****1****Description**

females urethral stricture

**Timepoint**

3 to 12 months after intervention

**Method of measurement**

Eurodynamic- questionnaire

**Secondary outcomes****1****Description**

normal voiding

**Timepoint**

3-12 months after intervention

**Method of measurement**

questionnaire

**2****Description**

Recurrence of symptoms

**Timepoint**

3-12 months after intervention

**Method of measurement**

questionnaire

**3****Description**

Create fistulas

**Timepoint**

3-12 months after intervention

**Method of measurement**

questionnaire and cystoscopy

**4****Description**

create Incontinence

**Timepoint**

3-12 months after intervention

**Method of measurement**

questionnaire

**5****Description**

Recurrence of stricture

**Timepoint**

3-12 months after intervention

**Method of measurement**

With Eurodynamics and Cystoscopy

**Intervention groups****1****Description**

Intervention group: Patients with urinary tract stenosis aged over 18 years who indicated stenosis treatment of the urinary tract and had no proper reaction to conservative, drug and dilatation therapies, or an unreliable uncertainty in the conduct of the abovementioned measures, and pvr was more than 100 they were prepared for orthoplasty using vaginal flaps. Patients are placed in the dorsal position of the lithotomy and foley catheter was inserted into the urinary bladder. the anterior wall of the vaginal two parallel incisions on the two sides of the meatus to the proximal maximal of 4 cm {depending on the length of the stenosis} are given and a 1.8 to 2 cm of the vaginal wall flap is dissected. Then the distal part of the flap is fluttered to the proximal flap and the inner part of the flap is tubularized over bigger size of foley catheter[20fr] with absorbable vicryl. The second layer of folded vaginal wall is sutured to native vagina with 3-0 vicryl. Then the foley catheter is removed after 2 weeks.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam reza hospital

**Full name of responsible person**

Prof. Sakineh Hajebrahimi

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Golgasht Street, Tabriz, Iran

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Hasan Soleimanpour

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Deputy of Research and Technology, Central Building of Number Two, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

90

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Hamed Marofi

**Position**

Resident of Urology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

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**Full name of responsible person**

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**Position**

Professor of Urology- Fellowship in Female Urology

**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Hamed Marofi

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Through publication as an article

**When the data will become available and for how long**

Through publication as an article

**To whom data/document is available**

Through publication as an article

**Under which criteria data/document could be used**

Through publication as an article

**From where data/document is obtainable**

Through publication as an article

**What processes are involved for a request to access data/document**

Through publication as an article

**Comments**

Through publication as an article