

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 - fistula 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 urethral 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

ebrahimis@tbzmed.ac.ir

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 vicryle. 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

Street address

Golgasht Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

+98 41 3335 7328

Phone

+98 41 3335 7328

Fax**Email**

hajebrahimis@gmail.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hasan Soleimanpour

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Email

hajebrahimis@gmail.com

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

Street address

Urology department, Educational and treatment center of Imam Reza, Golgasht Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

51666-14756

Phone

+98 41 3335 7328

Fax

+98 41 3335 2073

Email

hamedmarofi5@gmail.com

Position

Resident of Urology

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Urology department, Educational and treatment center of Imam Reza, Golgasht Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

04151666-14756

Phone

+98 984133357328

Fax

+98 41 3335 2073

Email

hamedmarofi5@gmail.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Prof. Sakineh Hajebrahimi

Position

Professor of Urology- Fellowship in Female Urology

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Department of Urology, Imam Reza educational and treatment center, Golgasht Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

04151666-14756

Phone

+98 984133357328

Email

hajebrahimis@gmail.com

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