

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of the relationship between End to End anastomotic urethroplasty and erectile dysfunction in the patients with urethral stricture referred to Shohada E Tajrish Hospital during 2014-2017: Single blind randomized clinical trial

Protocol summary

Summary

This study will be performed to evaluate the effect of end to end anastomotic urethroplasty on the sexual function in patients with urethral stricture. Inclusion criteria are consisted of: patients in active sexual age, patients with ability to follow up and candidate for this surgical procedure based on history, physical examination and radiographic and flexible cystoscopy findings. Exclusion criteria are consisted of: patients which will not have cooperation for follow up during performing the project, patients with endocrine disorders (Diabetes Mellitus, Thyroid dysfunction and dyslipidemia) and patients with hormonal disorders (such as testosterone and prolactin disorders). Population study are patients will undergo end to end anastomotic urethroplasty. Sampling is convenient and sample size will be 70 patients. All of patients will be undergo end to end urethroplasty in Shohada E Tajrish Hospital in Tehran during January 2016 till December 2017. Complete history, physical examination and complete laboratory data for sexual function will be fulfilled by questionnaire and patients checked by sexual function test questionnaire and color Doppler sonography of penile arteries before, 3 months and 6 months after surgery. Outcomes including radiographic findings to evaluate the pelvis fracture, site of urethral injury and perioperative bleeding, sexual function and color Doppler sonography of penile arteries will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021126513N1**

Registration date: **2016-05-10, 1395/02/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-10, 1395/02/21

Registrant information

Name

Morteza Fallahkarkan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3360 6767

Email address

karkan@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-01-01, 1394/10/11

Expected recruitment end date

2017-12-01, 1396/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the relationship between End to End anastomotic urethroplasty and erectile dysfunction in the patients with urethral stricture referred to Shohada E Tajrish Hospital during 2014-2017: Single blind randomized clinical trial

Public title

Relationship between performing operation on urethra on sexual dysfunction in patients with urethral stricture

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: patients in active sexual age; patients with ability to follow up; candidate for this surgical procedure based on history, physical examination and radiographic and flexible cystoscopy findings. Exclusion criteria: patients which will not have cooperation for follow up during performing the project; patients with endocrine disorders (Diabetes Mellitus, Thyroid dysfunction and dyslipidemia); patients with hormonal disorders (such as testosterone and prolactin disorders).

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

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

shahid beheshti medical university

Street address

velenjak

City

tehran

Postal code

Approval date

2016-01-19, 1394/10/29

Ethics committee reference number

IR.SBMU.SM.REC.1394.150

Health conditions studied

1

Description of health condition studied

Urethral Stricture

ICD-10 code

N37.8*

ICD-10 code description

Other urethral disorders in diseases classified elsewhere

Primary outcomes

1

Description

Erectile Dysfunction

Timepoint

Before, 3 and 6 months after surgery

Method of measurement

Penile color Doppler sonography with papaverine injection

Secondary outcomes

empty

Intervention groups

1

Description

Patients in one group will be assessed for indexes before and after End to End anastomotic urethroplasty.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada E Tajrish Hospital

Full name of responsible person

Behrooz Fadavi

Street address

Shohada E Tajrish Hospital, Tajrish Square, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Beside Taleghani Hospital, Shahid Abbas Erabi

(Parvane) Street, Yaman Street, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

IR.SBMU.SM.REC.1394.150

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Behruz Fadavi

Position

Urology Resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty