

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of locally injected Mitomycin-C after internal urethrotomy in treating urethral stricture.

#### Protocol summary

##### Summary

In this clinical trial study , 80 patients with urethral stenosis who underwent internal urethrotomy are reviewed & followed in Tehran Shohada hospital from Aban 94 to Shahrivar 96. Inclusion criteria are based on history and physical examination and radiographic & cystoscopic findings available ( in the short < 1.5 cm). People with long stenosis , penile stricture , such as Balanitis Xerotica Obliterans (BXO) and Benign Prostatic Hyperplasia (BPH) will be excluded . Patients will be selected based on thorough history and physical examination and questionnaire prepared by radiographic studies ( for anterior strictures ). Patients will undergo Star-like internal urethrotomy under anesthesia and under the dorsal lithotomy position. The patients were divided into two groups and submucosal injection of 0.1mg / 2cc mitomycin- C with 22-Gauge needle will be done for half of patients . Postoperative catheter is inserted for five days . Then patients symptoms & uroflowmetry findings after removing the catheter and also 6 months after will be evaluated; if abnormal results (Q-max <15 obstructive pattern ), Retrograde UrethroGram - Voiding CystoUrethroGram (RUG-VCUG) and , if necessary, carry out and patency and the need for internal urethrotomy and dilatation will be reviewed and , if necessary, up to once again undergo incision & re- injection of mitomycin-C .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015092724225N1**  
Registration date: **2017-04-08, 1396/01/19**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-04-08, 1396/01/19

##### Registrant information

###### Name

Saman Najafi

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2291 2156

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Infertility and Reproductive Health Research Center  
Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2015-10-23, 1394/08/01

##### Expected recruitment end date

2017-03-20, 1395/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of locally injected Mitomycin-C after internal urethrotomy in treating urethral stricture.

##### Public title

Mitomycin effect in the treatment of urethral stenosis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: stenosis length <1.5 cm Exclusion

criteria: Long stricture, shortness of penile, such as BXO and BPH

**Age**

No age limit

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 80

**Randomization (investigator's opinion)**

Randomized

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Infertility and Reproductive Health Research Center  
Shahid Beheshti University of Medical Sciences

**Street address**

Taleghani Hospital

**City**

Tehran

**Postal code****Approval date**

2015-05-27, 1394/03/06

**Ethics committee reference number**

400/719

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

urthral stenosis

**ICD-10 code**

N35

**ICD-10 code description**

Urethral Stricture

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

Improving Urine voiding

**Timepoint**

Immediately after the intervention, and six months after intervention

**Method of measurement**

Uroflowmetry- RUG-VCUG - Cystoscopy

**Secondary outcomes**

empty

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

In intervention group, internal urethrotomy is done for patients with urethral stricture; then 0.1mg/2cc mitomycin-c is injected submucosally with needle 22-gauge in incision sites; and after that urethral catheter is inserted for one week.

**Category**

Treatment - Drugs

**2****Description**

In control group, internal urethrotomy is done for patients with urethral stricture; and then urethral catheter is inserted for one week.

**Category**

Treatment - Surgery

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

Shohada-ye Tajrish Hospital

**Full name of responsible person**

Dr.Saman Najafi

**Street address**

Shohada-ye Tajrish Hospital

**City**

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

Infertility and Reproductive Health Research Center

**Full name of responsible person**

Mrs.Zahra Sadeghzadeh

**Street address**

Taleghani Hospital

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Infertility and Reproductive Health Research Center

**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**

Infertility and Reproductive Health Research Center

**Full name of responsible person**

Dr.Saman Najafi

**Position**

Physician/Urology Resident

**Other areas of specialty/work**

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Dr.Seyyed Jalil Hosseini

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**Other areas of specialty/work**

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**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*