

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 Obliterance (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)

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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

Tehran

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

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Position

Physician/Urology Resident

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saman Najafi

Position

Physician/ 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