

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### A clinical trial to compare the effectiveness of oral colchicine and placebo on the need for urethral dilation after internal urethrotomy

#### Protocol summary

##### Study aim

The effectiveness of oral colchicine and placebo on the need for urethral dilation after internal urethrotomy

##### Design

Totally, 176 patients with narrowing of the urethra candid for internal urethrotomy were chosen from the Ghaem Hospital, Mashhad, Iran. In this triple-blind, controlled clinical trial, the patients are assigned into parallel groups using simple and successive sampling methods.

##### Settings and conduct

Patients with narrowing of the urethra candid for internal urethrotomy who are candidates for internal urethrotomy at the Ghaem Hospital, Mashhad, Iran, are chosen. In this triple-blind study, sealed opaque envelopes will be used to conceal the sequencing. The participants, person responsible for data collection, and clinical care provider are blind to group allocation and the type of drugs.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: narrowing shorter than 1 centimeter in bulbar urethral stricture; single urethral strictures; first-time visitor; age over 20 years. Exclusion criteria: sensitivity to colchicine; having gastrointestinal problems; the history of liver failure; the history of renal disease.

##### Intervention groups

The intervention group will receive 1 mg oral colchicine after internal urethrotomy for 6 weeks. The control group will receive 1 mg oral placebo (Placebo will be produced the same of colchicine in terms of shape, size, taste, color, and odor by pharmaceutical company) after internal urethrotomy for 6 weeks.

##### Main outcome variables

Evaluation and comparison of the rate of urethral stricture, symptoms of acute urinary, and the rate of pain 6 weeks and 3 months after intervention in control and intervention groups.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200628047937N1**

Registration date: **2020-08-12, 1399/05/22**

Registration timing: **prospective**

Last update: **2020-08-12, 1399/05/22**

Update count: **0**

##### Registration date

2020-08-12, 1399/05/22

##### Registrant information

##### Name

Samane Shirzadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3760 4106

##### Email address

shirzadis921@mums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2021-03-10, 1399/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial to compare the effectiveness of oral colchicine and placebo on the need for urethral dilation after internal urethrotomy

**Public title**

Effect of oral colchicine on urethral dilation control

**Purpose**

Treatment

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

Narrowing shorter than 1 centimeter in bulbar urethral stricture Single urethral strictures First-time visitor Age over 20 years

**Exclusion criteria:**

Sensitivity to colchicine Having gastrointestinal problems The history of liver failure The history of renal disease

**Age**

From **20 years** old

**Gender**

Male

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **176**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The subjects will be randomly assigned into two groups of 88 patients with blocks of 2 and 4 using randomization method. A noninvolved researcher will determine the random assignment sequencing in sample selection based on a statistical analysis system (SAS), computer software. Accordingly, the participants were given codes and assigned into the intervention and control groups

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The participants, person responsible for data collection, and clinical care provider are blind to group allocation and the type of drugs.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Mashhad University of Medical

Sciences

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9195965919

**Approval date**

2020-06-07, 1399/03/18

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1399.093

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

Urethral dilation

**ICD-10 code**

N36.8

**ICD-10 code description**

Other specified disorders of urethra

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

Urethral stricture

**Timepoint**

6 weeks and 3 months after intervention

**Method of measurement**

Retrograde urethrography

**2****Description**

Symptoms of acute urinary

**Timepoint**

6 weeks and 3 months after intervention

**Method of measurement**

Clinical urine tests

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

The rate of pain

**Timepoint**

6 weeks and 3 months after intervention

**Method of measurement**

Analogue Scale for Pain (VAS)

**Intervention groups**

## 1

### Description

Intervention group: The intervention group will receive 1 mg oral colchicine after internal urethrotomy for 6 weeks.

### Category

Treatment - Drugs

## 2

### Description

Control group: The control group will receive 1 mg oral placebo (Placebo will be produced the same of colchicine in terms of shape, size, taste, color, and odor by pharmaceutical company) after internal urethrotomy for 6 weeks.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital

##### Full name of responsible person

Samane Shirzadi

##### Street address

Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9187145785

##### Phone

+98 51 3760 4106

##### Email

Shirzadi.samane73@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Email

vcresearch@mums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Mashhad University of Medical Sciences

##### Proportion provided by this source

100

##### 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Samane Shirzadi

##### Position

Internship

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Practitioner

##### Street address

Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9187145785

##### Phone

+98 51 3760 4106

##### Email

Shirzadi.samane73@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Samane Shirzadi

##### Position

Internship

##### Latest degree

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9187145785

**Phone**

+98 51 3760 4106

**Email**

Shirzadi.samane73@gmail.com

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Samane Shirzadi

**Position**

Internship

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9187145785

**Phone**

+98 51 3760 4106

**Email**

Shirzadi.samane73@gmail.com

**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**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

Information on the main outcome or the like can be shared

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

6 months after printing results

**To whom data/document is available**

Our data will only be available to researchers working at science centers and universities.

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

Our data will be available for scholars working at science centers and universities.

**From where data/document is obtainable**

Samane Shirzadi provides the data analysis to the applicants via email: Shirzadi.samane73@gmail.com

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

Applicants can respond to the email of the respondent and receive a response within a week.

**Comments**