

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

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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**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

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