

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation of the effect of injectable dexamethasone on the frequency and excretion time of distal ureteral stones

Protocol summary

Study aim

Determining the effect of injectable dexamethasone administration on the frequency and excretion time of distal ureteral stones

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 100 patients

Settings and conduct

In this randomized double-blind clinical trial study, 100 eligible patients referred to Al-Zahra Hospital in Isfahan will be included in the study and randomly divided into two groups. Patients in the first group will be prescribed dexamethasone and in the control group distilled water. Then the frequency and time of stone excretion will be compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include definitive diagnosis of distal ureteral stone less than 1 cm, age over 18 years, drug indication, and consent to participate in the study. Exclusion criteria include benign prostatic hyperplasia (BPH), concomitant stenosis, contraindications to corticosteroids, and hydronephrosis.

Intervention groups

Intervention group 1: Patients in this group are treated orally with tamsulosin 0.4 mg/day for two weeks. In addition, an intramuscular injection of 8 mg dexamethasone will be given. Control group: Patients in this group receive oral tamsulosin 0.4 mg/day for two weeks. In addition, 8 mg of distilled water will be injected intramuscularly within a week.

Main outcome variables

Frequent distal ureteral stone excretion, Time to excrete distal ureteral stones

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N59**

Registration date: **2022-09-12, 1401/06/21**

Registration timing: **prospective**

Last update: **2022-09-12, 1401/06/21**

Update count: **1**

Registration date

2022-09-12, 1401/06/21

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-21, 1401/06/30

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of injectable dexamethasone on the frequency and excretion time of distal ureteral stones

Public title

Evaluation of the effect of injectable dexamethasone on excretion of distal ureteral stones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of distal ureteral stones below 1 cm
Age over 18 years Indicated for drug therapy Satisfaction to participate in the study

Exclusion criteria:

Having benign prostatic hyperplasia (BPH) at the same time Having a narrowing of the urethra Contraindications to the use of corticosteroids Existence of hydronephrosis

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

En In this study, 100 eligible patients are randomly selected. For this, the letter A is written on 50 sheets, the letter B is written on 50 sheets, and each is placed in an envelope. Each patient is then asked to choose one of the envelopes. The patient is assigned to one of two groups depending on the selected envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, two drugs, dexamethasone, and distilled water, are pre-prepared in similar syringes of the same volume and placed in coded packages, and delivered daily to the researcher. The researcher prescribes each drug without knowing the type. Also, the person recording the patient and clinical information and the statistical analyst will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave, Azadi Square.

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Isfehan

Postal code

8174673461

Approval date

2021-04-10, 1400/01/21

Ethics committee reference number

IR.MUI.MED.REC.1400.015

Health conditions studied

1

Description of health condition studied

Calculus of ureter

ICD-10 code

N20.1

ICD-10 code description

Calculus of ureter

Primary outcomes

1

Description

Frequent distal ureteral stone excretion

Timepoint

Until the end of two weeks of intervention

Method of measurement

Observational

2

Description

Time to excrete distal ureteral stone

Timepoint

Until the end of two weeks of intervention

Method of measurement

Observational

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group are treated orally with Tamsulosin 0.4 mg / day for two weeks. In addition, an intramuscular injection of 8 mg

dexamethasone will be given.

Category

Treatment - Drugs

2**Description**

Control group: Patients in this group receive oral tamsulosin 0.4 mg / day for two weeks. In addition, 8 mg of distilled water will be injected intramuscularly within a week.

Category

Placebo

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

Al-Zahra Hospital

Full name of responsible person

Reza Kazemi

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

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

No

Title of funding source

Isfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Reza Kazemi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available