

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of potassium citrate administration on type of stone on ureteral stents compared with primary stone

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The effect of potassium citrate administration on type of stone on ureteral stents compared with primary stone

Last update: **2020-06-20, 1399/03/31**

Update count: **0**

Design

Clinical trial with two parallel groups without blinding, simple randomization

Registration date

2020-06-20, 1399/03/31

Settings and conduct

This clinical trial will be performed in Sina Hospital. Patients will be divided into control and intervention groups by simple randomization method. One group was treated with potassium citrate daily and the other group was not treated. The stones removed by the laboratory are checked for material. The DJ stent is also checked for leaks and stones after leaving. The difference between the material and the composition of the stone and the castration on the stent is also investigated in people who consume potassium citrate with people who do not consume potassium citrate.

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

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mkaghamir@tums.ac.ir

Participants/Inclusion and exclusion criteria

Inclusion criteria: all people who had a Stent Dj after having kidney stones treated. Exclusion criteria: the stone is not formed on the Dj; people who don't want to leave Dj; the stone is not formed on the Dj.

Recruitment status

Recruitment complete

Funding source

Intervention groups

One group was treated with potassium citrate daily and the other group was not treated.

Expected recruitment start date

2020-03-10, 1398/12/20

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

How long does a DJ stent last? Combining the patient's primary stone The composition of the stone formed on the Dj stent is due to the presence of citrate and the absence of citrate Number of doses of potassium citrate

Scientific title

The effect of potassium citrate administration on type of stone on ureteral stents compared with primary stone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043991N6**

Registration date: **2020-06-20, 1399/03/31**

Public title

The therapeutic effect of potassium citrate on the type of stone formed on ureteral stents

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All people who had a Stent Dj after having kidney stones treated

Exclusion criteria:

People who don't have a DJ. People who don't want to install a DJ. The stone is not formed on the Dj.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

In block randomization, patients are divided into two groups. One group was treated with potassium citrate daily and the other group was not treated.

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

Ethics Committees in Medical Medical Research

Street address

Room 604, Sixth Floor, Central Staff Building, Tehran
University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-02-04, 1398/11/15

Ethics committee reference number

IR.TUMS.VCR.REC.1398.902

Health conditions studied

1

Description of health condition studied

Urinary stones

ICD-10 code

N20.2

ICD-10 code description

Calculus of kidney with calculus of ureter

Primary outcomes

1

Description

The composition of the stone formed on the Di stent is due to the presence of citrate and the absence of citrate.

Timepoint

Immediately after leaving Dj

Method of measurement

Pathology and Stone Detection Laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, after the stone operation and the installation of a DJ, they were treated with potassium citrate 30 mg daily.

Category

Treatment - Drugs

2

Description

Control group: In this group, they did not receive potassium citrate after the stone operation and the installation of a DJ.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Mohammad Kazem Aghamir

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Hassan Abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr Akram Mirzaei
Position

Researcher
Latest degree
Ph.D.
Other areas of specialty/work
Molecular Medicine
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Person responsible for scientific inquiries

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Position
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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

demographic information anonymously

When the data will become available and for how long

one year after publication

To whom data/document is available

Researchers working in academia, physicians, surgeons and hospitals

Under which criteria data/document could be used

Re-information for the purpose of clarification Using data by referring to the article's original Get permission from the author of the article and the presenter

From where data/document is obtainable

Sina Hospital, Urology Research Center, Head of Urology Research Center: Dr. Seyed Mohammad Kazem Aghamir 00982166348560

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

After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.

Comments

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