

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the effects of potassium citrate and hydrochlorothiazide on the stone formation rate of ureteral stent in patients with prolonged stent insitue in Imam Khomeini Hospital urmia

Protocol summary

Study aim

Evaluation of potassium citrate and hydrochlorothiazide effect on stone formation rate of ureteral stent in patients who needs ureteral stent for long time

Design

A randomized controlled clinical trial, double-blind, with parallel groups, on 130 patients

Settings and conduct

after approval by the University Ethics and Research Committee, 130 patients who will require open or closed urologic surgery which needs ureteral stent be insitu for at least 4 weeks After obtaining informed consent will be included in our study, two equal groups of patients will be entered in our study. group 1 will be patients whith even chart number (control group) and group 2 intervention group with Odd chart number which receive hydrochlorothiazide and potassium citrate but the other group will not receive any medication.The researcher will not be aware of the groups receiving the drugs. All stents will be in same brand and the maximum instu duration for 6 weeks

Participants/Inclusion and exclusion criteria

- 1.Patients who have 18-65 years old under went urologic surgeries which needs ureteral stent insitu for 4weeks
- 2.absence of urinary tract infection
3. Absence of metabolic abnormality such as primary or secondary hyperparathyroidism,
- 4.absence of Ca and Vitamin D supplements usages

Intervention groups

In intervention group Hydrochlorthiazide 50mg PO Daily and one teaspoon of Citratpotassium powder inside the glass of water, three times a day after meal beside the usual post-operation drugs such as acetaminophen and ciprofloxacin will be given, but in control group only acetaminophen and ciprofloxacin will be given

Main outcome variables

Stent Encrustation , duration of stent insitu

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180625040232N3**

Registration date: **2020-04-19, 1399/01/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-19, 1399/01/31**

Update count: **0**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

Saman Farshid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

farshid.s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of potassium citrate and hydrochlorothiazide on the stone formation rate of ureteral stent in patients with prolonged stent insitue in Imam Khomeini Hospital urmia

Public title

Comparison of the effects of potassium citrate and hydrochlorothiazide on the stone formation rate of ureteral stent in patients with prolonged stent insitue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have 18-65 years old under went urologic surgeries which needs ureteral stent insitu for 4weeks absence of urinary tract infection Absence of metabolic abnormality such as primary or secondary hyperparathyroidism, absence of Ca and Vitamin D supplements usages

Exclusion criteria:

Patient age less than 18 or more than 60 stent placement for less than 4 weeks urinary tract infection metabolic abnormality such as primary or secondary hyperparathyroidism, Ca and Vitamin D supplements usages patients who do not have intend to use Drugs that are prescribed for Stone formation prevention

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and our analyzer team will be blinded about the patients whom received citratpoatassium and hydrochlorthiazide , patients will be allocated to drug or control group according to chart number, patients with even chart number in control group and patients with odds chart number in intervention group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committe of Urmia University of medical Sciences

Street address

Ershad Ave.,Urmia,West Azarbaijan,Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2017-07-19, 1396/04/28

Ethics committee reference number

ir.umsu.rec.1396.130

Health conditions studied

1

Description of health condition studied

ureteral stent complication :stent encrustation

ICD-10 code

T83.192A

ICD-10 code description

Other mechanical complication of urinary stent, initial encounter

Primary outcomes

1

Description

Stent Encrustation

Timepoint

4 weeks after ureteral stent insertion

Method of measurement

observation of ureteral stent encrustation during stent extraction with difficult stent extraction due to stent encrustation

Secondary outcomes

1

Description

stent insitu duration

Timepoint

End of intervention ,at the time of stent extraction

Method of measurement

By reviewing the date of surgery and stent insertion from the summary chart at the time of referring to stent extraction

Intervention groups

1

Description

Intervention group: to patients undergoing urologic surgeries which are needed ureteral stent instu for 4 weeks , One Teaspoon potassium citrate powder inside the glass of water three times a day after meal with Hydrochlorothiazide 50 mg daily were prescribed

Category

Treatment - Drugs

2

Description

Control group: patients undergoing urologic surgeries which are needed ureteral stent instu for 4 weeks that usually do not receive any drug

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini Hospital Urmia

Full name of responsible person

Hadi Ranjbar

Street address

Imam Hospital , Ershad Ave., Urmia

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hadiranjbar7011@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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Setad Olumpezeshki Urmia, Reasalat Ave., Urmia

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Mohebbi_Iraj@yahoo.co.uk

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Saman Farshid

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

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Full name of responsible person

Saman Farshid

Position

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Any information without the need for patients' names will be available

When the data will become available and for how long

6 months after publication in journals

To whom data/document is available

medical faculty members

Under which criteria data/document could be used

For research purposes

From where data/document is obtainable

samanf63@gmail.com farshid.s@umsu.ac.ir

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

By sending an email to samanf63@gmail.com

Comments