

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of the combined effect of potassium citrate consumption and the comparison of double j stent in reducing the formation of urinary tract stones

Protocol summary

Study aim

Evaluation of the effect of potassium citrate administration on re-formation of stones on double j ureteral stents

Design

Using the online site sealedenvelop.com (a site for sequencing randomized block), random blocks of patients in two groups A: Double j plus placebo B: Double j plus potassium citrate. The order of patient placement is provided to the technician. The study is Double blind (patient and surgeon). 70 patients referred to Sina Hospital will be studied. The study is interventional, phase 3, parallel and therapeutic.

Settings and conduct

This clinical trial will be performed on 70 patients at Sinai Hospital. All patients undergoing tul and pcnl and double j implantation are divided into two target groups (group A: double j plus placebo B: double j plus potassium citrate).double blind (patient and surgeon),Technician (importer of patients in each group based on random blocks), quadruple blocks are randomly made for patients in groups A and B, 17 quadruple blocks that are placed in separate envelopes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all people who had a Stent Dj after having kidney stones treated. Exclusion criteria: Having diabetes with poor blood control,Digoxin for heart problems,Concomitant use of calcium supplements,Taking potassium-sparing diuretics,Previous history of hypercalcemia,use of Levodopa,Blood sugar above 160 mg two hours after a meal despite taking diabetes medications,Take any amount of spironolactone, triamterene and amiloride tablets,High blood potassium more than 5,GFR less than 70,Pregnancy

Intervention groups

Intervention group A: Patients receiving Double j with

placebo. Intervention groupB: Patients receiving double j in addition to potassium citrate.

Main outcome variables

Re-formation of stone on Dj stent due to the presence of citrate and the absence of citrate

General information

Reason for update

Acronym

TUL)Lithotripsy Ureteral Trans

IRCT registration information

IRCT registration number: **IRCT20190624043991N8**

Registration date: **2020-08-11, 1399/05/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-11, 1399/05/21**

Update count: **0**

Registration date

2020-08-11, 1399/05/21

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-28, 1399/04/08

Expected recruitment end date

2021-05-29, 1400/03/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the combined effect of potassium citrate consumption and the comparison of double j stent in reducing the formation of urinary tract stones

Public title
The effect of potassium citrate and double j stent in reducing stone formation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients undergoing tulle (Trans Ureteral Lithotripsy).
 Patients undergoing pcnl (Percutaneous nephrolithotomy). Patients with Double j.
Exclusion criteria:
 Having diabetes with poor blood control Digoxin for heart problems Concomitant use of calcium supplements
 Taking potassium-sparing diuretics Previous history of hypercalcemia use of Levodopa Blood sugar above 160 mg two hours after a meal despite taking diabetes medications Take any amount of spironolactone, triamterene and amiloride tablets High blood potassium more than 5 GFR less than 70 Pregnancy

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: 70

Randomization (investigator's opinion)
Randomized

Randomization description
The present study is a double-blind randomized clinical trial. For randomization, the blanced block randomization method is used to generate quadruple blocks. According to the randomization method, we expect the two groups to differ by a maximum of 2 people in terms of the number of people assigned. After the methodologist prepares the randomization sequence using the sealdenvelop online site, the generated sequence will be made available to a technician outside the research team. Quadruple blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected and the type of patient group is informed to the research team through a trained technician. Based on the randomly selected envelope, the patient is placed in the

(A) double j plus placebo or (B) double j plus potassium citrate treatment group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients who have agreed to participate in the study and the therapist for the blinding process, envelopes related to the type of intervention are provided only to the technician. The physician (to avoid bias) and the patient are not informed of the type of intervention (double j plus placebo or double j plus potassium citrate).

Placebo
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

2020-06-28, 1399/04/08

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1399.007

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

Re-formation of stone on Dj stent due to the presence of citrate and the absence of citrate

Timepoint

Immediately after leaving Dj stent

Method of measurement

Pathology and Stone Detection Laboratory

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients receiving Double j with placebo.

Category

Treatment - Drugs

2**Description**

Intervention group: Patients receiving double j in addition to potassium citrate.

Category

Treatment - Drugs

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

Sina Hospital

Full name of responsible person

Dr seyed mohammad kazaem aghamir mohammadali

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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

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Tehran. Keshavarz Boulevard, Quds Ave., Central University, Sixth Floor

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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

Medical Biology

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Position

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Latest degree

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Other areas of specialty/work

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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