Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparison the effect of single dose medication in decreasing urgent ureteroscopy complications, a double blind randomized clinical trial

Protocol summary

Study aim
Effect of prescription of drugs on acute complications of Transurethral Lithotripsy

Design
In this parallel clinical trial, block randomization is performed using an online program. In phase 3, 3 medications and a placebo are used to assess the efficacy of different medications in decreasing transurethral lithotripsy complications in 400 patients.

Settings and conduct
In this study, at Sina Hospital in Tehran, patients who are candidates for transurethral lithotripsy are randomly and blindly divided into four groups, and with three drugs in three groups and in group four without drugs, the prevalence of intervention complications is assessed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: TUL candidate patients Exclusion criteria: Previous ureteral manipulation Having a DJ (Double J) or ureteral catheter Creatinine above 1.5 mg / dL Age over 65 years Weight less than 50 kg Contraindications or allergies to prescribed drugs Patients who are taking one of the above three drugs for any reason before seeking TUL. Patient dissatisfaction with participating in the research project

Intervention groups
Four drug groups (tamsulosin, serum normal saline, ketorolac, and hyoscine) The first group received only one liter of normal saline (placebo) before TUL. The second group received tamsulosin capsules two nights before surgery. The third group received ketorolac before TUL with one liter of normal saline at least one hour before surgery. The fourth group received an ampoule of hyoscine with one liter of normal saline at least one hour before TUL.

Main outcome variables
Bladder injury, Ureterovesical junction injury, ureteral mucosa elevation, ureteral perforation, inability to reach the ureteral stone, inability to enter the ureter, ureteral avulsion, and need for a narrower ureteroscope

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161221031505N1**
Registration date: **2022-06-25, 1401/04/04**
Registration timing: **prospective**

Last update: **2022-06-25, 1401/04/04**
Update count: **0**

Registration date
2022-06-25, 1401/04/04

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 556585015
Email address
h-akhavizadegan@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of single dose medication in

decreasing urgent ureteroscopy complications, a double blind randomized clinical trial

Public title
Assessing the efficacy of different medications in decreasing complications of transureteral lithotripsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates of transureteral lithotripsy
Exclusion criteria:
Renal dysfunction, Creatinine more than 1.5 mg/dl Previous ureteral intervention Having Double J or ureteral catheter age higher than 65 Weight less than 50 kg Contraindication or allergy to medications used in project History of using medications before intervention Patient does not want to participate in study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **400**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization In this section using the site (https://www.sealedenvelope.com/simple-randomiser/v1/lists) randomization is done with quadruple blocks (equal to the number of groups). The list of each of four patients is entered in a block, respectively. The first and second-year urology assistants who are responsible for preparing the patient in the urology ward will give the necessary dose to the patient and record it and then the patient is transported to the operating room without knowing about the medicine received.
Blinding (investigator's opinion)
Double blinded
Blinding description
The medication is prescribed and registered by the first-year assistant in the ward without mentioning its name to the patient and the stone crushing is done by the third-year assistant in the operating room without knowing the medication.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Tehran University of Medical Sciences
Street address
Sina hospital, Hasn Abad square,
City
Tehran
Province
Tehran
Postal code
1136746911
Approval date
2020-08-27, 1399/06/06
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.371

Health conditions studied

1

Description of health condition studied
Ureteral stone
ICD-10 code
ICD-10 code description
N 21

Primary outcomes

1

Description
Reducing damage to the bladder
Timepoint
During TUL
Method of measurement
Observing procedure

2

Description
Reducing damage to the ureteral entrance to the bladder
Timepoint
During TUL
Method of measurement
Observing procedure

3

Description
Reducing ureteral mucosa injury
Timepoint
During transurethral lithotripsy
Method of measurement
Observing the procedure

4

Description
Reducing ureteral perforation
Timepoint
During transurethral lithotripsy
Method of measurement
Observing the procedure

5

Description
Reducing ureteral stone riching failure
Timepoint
During transurethral lithotripsy
Method of measurement
Observation the procedure

6

Description
Reducing inability to enter the ureter
Timepoint
During transurethral lithotripsy
Method of measurement
Observation during procedure

7

Description
Reducing ureteral avulsion
Timepoint
During transurethral lithotripsy
Method of measurement
Observing during procedure

8

Description
Reducing the need for a narrower ureteroscope
Timepoint
During transurethral lithotripsy
Method of measurement
Observing during procedure

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group number 1: 1 amp. Hyoscine 20 mg made by Exir company diluted in one liter normal saline is infused via vein catheter 1 hour before intervention.
Category
Treatment - Drugs

2

Description
Intervention group number 2: 1 amp. ketorolac 30 mg made by Exir company diluted in one liter normal saline is infused via vein catheter 1 hour before intervention.
Category
Treatment - Drugs

3

Description
Intervention group number 3: 2 caps. Tamsulosin made by Exir company is prescribed for the patient and tomorrow one liter normal saline is infused via vein catheter during one hour before surgery.
Category
Treatment - Drugs

4

Description
Control group or intervention 4: 1 liter normal saline is infused one hour before surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Hamed Akhavizadegan
Street address
Hasan abad Square
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Email
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Web page address
https://sinahospital.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhoondzadeh
Street address
Research Deputy office, Tehran University of Medical Sciences, Boulevard Keshavarz
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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
30

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
Hamed Akhavizadegan

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Urology

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Hasan Abad square, Sina hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Hamed Akhavizadegan

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
Urology

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be 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
All data will be provided to the Vice-Chancellor for Research of Tehran University of Medical Sciences as a dissertation

When the data will become available and for how long
6 months after the publication of the article

To whom data/document is available
Scientific institutes and researchers

Under which criteria data/document could be used
To share experiences and increase citations

From where data/document is obtainable
To the e-mail address of Dr. Hamed Akhvizadegan (h-akhavizadegan@tums.ac.ir)

What processes are involved for a request to access data/document
Up to one month after the email and review of the application and then obtaining the license of the Vice Chancellor for Research, information will be provided to the person.

Comments
In addition, because the research is a dissertation, a copy of it is available to the public in the Central Library as well as in the library of Sina Hospital.