Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of success rate and complications of transureteral lithotripsy for uncomplicated ureteral stones with or without safety guide wire

Protocol summary

Study aim
Comparison of success rate and complications of transureteral lithotripsy in uncomplicated ureteral stones with or without safety guide wire

Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment, sample size 348

Settings and conduct
After splitting the patients randomly into groups A and B. in group A, ureteroscopy is done after the ureteral guide wire is inserted, the guide wire remains in the system, and the lithotripsy is performed in the presence of the guide wire. In group B patients, ureteroscopy is performed on the guide wire and after reaching the stone, the guide wire is removed lithotripsy is performed. After breaking the stone into pieces that are disposable to the size of a lithoclast probe, the operation ends. In the event of possible injury to the ureter or edema of the tissue or suspicion to a large number of ureteral stone fragments, a Double-J stent is inserted and reported and recorded. All patents are fallowed for one month after surgery and any complications such as pain, fever and peritonitis is recorded. At the end all data will be given to statistics specialist for analysis

Participants/Inclusion and exclusion criteria
All male and female patients; need to spectroscopy or TUL; aged 20 years or above; willing to participate in this clinical trial

Intervention groups
The first group: before endoscopic ureteral lithotripsy, a safety wire is inserted into the ureter and then lithotripsy is performed. The second group: endoscopic ureteral lithotripsy without embedded safety guide wire is performed.

Main outcome variables
Ureteral injury (ureteral perforation or rupture); complete stone clearance; Need for ureteral stent placement; Duration of operation; Delayed ureteral stenosis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200129046298N1**
Registration date: **2020-03-11, 1398/12/21**
Registration timing: **prospective**

Last update: **2020-03-11, 1398/12/21**
Update count: **0**

Registration date
2020-03-11, 1398/12/21

Registrant information

Name
Reza Behzadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-15, 1398/12/25

Expected recruitment end date
2021-04-21, 1400/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of success rate and complications of transureteral lithotripsy for uncomplicated ureteral stones with or without safety guide wire

Public title
Comparison of success rate and complications of transureteral lithotripsy for uncomplicated ureteral stones with or without safety guide wire
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All male and female pateints Need to uretroscopy or TUL Age at least 20 years Willing to participate in this study
Exclusion criteria:
1. Presence of fever or positive urine culture prior to surgery 2. History of ureteral trauma or ureteral re-implantation or open stone surgery in the same side 3. Patients with renal transplantation 4. History of severe immunodeficiency and coagulopathy 5. Circumstances that make safety wire insertion mandetory (ie. Ureteral severe edema, ureteral stricture, abnormal anatomy, stone street.) 6. History of radiotherapy
Age
From **20 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **348**
Randomization (investigator's opinion)
Randomized
Randomization description
Each patient is assigned to A or B group immediately prior to surgery by computer software that make one of letters A or B randomly. The researcher is unaware of the procedure assigned to each of A or B
Blinding (investigator's opinion)
Double blinded
Blinding description
Neither the patents nor the researcher and the data analyzer know the used surgical technique .
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Gharani street, shahid bahonar hospital
City
Kerman
Province
Kerman
Postal code
7613747181
Approval date
2020-01-25, 1398/11/05
Ethics committee reference number
IR.KMU.REC.1398.560

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
pain after surgery
Timepoint
one day after surgery
Method of measurement
VAS ruler

2

Description
ureteral injury
Timepoint
In case of clinical suspicion of severe ureteral injury, an imaging scan is performed as soon as possible after surgery.
Method of measurement
IVU imaging

3

Description
stone free rate
Timepoint
one day post surgery
Method of measurement
KUB or sonography imaging

4

Description
ureteral stent placement
Timepoint
immediately after surgery
Method of measurement
presence of ureteral edema or injury or stone residue

5

Description
post surgry fevers
Timepoint
Immediately after surgery until 10 days after surgery daily
Method of measurement
thermometer

6

Description
acute abdomen
Timepoint
from immediately after surgery until 10 days after surgury
Method of measurement
physical examination

7

Description
Body mass index (BMI)
Timepoint
before surgury
Method of measurement
from BMI formula

8

Description
stone size
Timepoint
before surgery
Method of measurement
based on imaging(sonography or CT scan)

9

Description
stone location
Timepoint
before surgery
Method of measurement
ct scan or sonography

10

Description
surgical time
Timepoint
during surgery
Method of measurement
minutes

11

Description
new ureteral stenosis
Timepoint
one month after surgery
Method of measurement
IVU

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: not using the safety guide wire before trans ureteral lithotripsy. In this group the Lithotripsy will be started as soon as the stone is spotted in endoscopy and no more manipulation is done
Category
Treatment - Surgery

2

Description
Control group: using safety guide wire. In this group, as soon as the stone is reached, the safety weir is secured from the side of the stone through the ureter into the pelvis, then the endoscope is removed, and the ureteroscopy is performed again from the side of the wire to the location of the stone, and then the lithotripsy is performed.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Bahonar hospital (urology department)
Full name of responsible person
Dr. Hamid Pakmanesh
Street address
Gharani st. - Shahid Bahonar hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Reza Behzadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Urology
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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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 potential data can be shared after unidentificaton people

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available
It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used
All additional statistical analysis is permitted

From where data/document is obtainable
Coordinate with Dr. Pakmanesh on the technical responsibility of the project

What processes are involved for a request to access data/document
After the agreement of Kerman University of Medical Sciences as the main sponsor of the project, datas will be available

Comments