Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial comparing the success and complications of emergency and elective ureteroscopy for treatment of ureteral stones

Protocol summary

Study aim

Evaluation of the success and complications of emergency treatment of endoscopic ureteral stone compared with delayed treatment

Design

All patients with acute renal colic fulfilled inclusion criteria will be interviewed and will be randomly assigned if they agree to be included in the study. The patient will then receive the appropriate treatment based on the type of allocation group assigned. Random allocation will be used via minimization procedure where the initial allocation treatment (first 40 cases) is based on a table of random number, subsequent allocations (from patient 41 onward) are based on a minimization protocol that has a relatively equal sample size in the two groups

Settings and conduct

This study will be a randomized clinical trial with two parallel groups at hasheminejad hospital.Patient are included in this study of patient with renal type painand urinary stone imaging studies

Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients over 15 years of age and under 80 years with ureteral stones greater than 6 mm and with normal creatinine, with renal colic from up to one week prior. exclusion criteria: renal failure(GFR<30), Fever above 38 °C, single kidney, history of ureteral stenosis, leukocytosis above 20,000, and definitive indications of immediate intervention according to the European guideline (associated with urinary tract infection and obstructive uropathy or aneuria) and aspirin and /or anticoagulant drugs use

Intervention groups

Case Group: Includes patients in the immediate emergency ureteroscopic treatment who undergo ureteroscopy within 24 hours of ED visit. Control Group: includes patients receiving unsuccessful stone expulsive (plus analgesic) therapy for 3 to 4 weeks who will undergo ureteroscopic treatment then

Main outcome variables

Loss of work days, Severity of pain, Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190720044279N1**
Registration date: **2020-06-09, 1399/03/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-09, 1399/03/20**
Update count: **0**

Registration date

2020-06-09, 1399/03/20

Registrant information

Name

Pejman Shadpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8864 4485

Email address

shadpour.p@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-09, 1399/03/20

Expected recruitment end date

2020-09-10, 1399/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A clinical trial comparing the success and complications of emergency and elective ureteroscopy for treatment of ureteral stones

Public title
Comparison of the success and complications of emergency and elective ureteroscopy for treatment of ureteral stone

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients with acute renal colic who are over 15 years and under 80 years ureteral stone larger than 6 mm normal creatinine
Exclusion criteria:
Kidney failure (GFR less than 30) Fever above 38 ° C single kidney A history of ureteral stricture Leukocytosis above 20,000 and definitive indications of immediate intervention according to the EAU guideline (associated with urinary tract infection, obstructive uropathy or anuria) aspirin and/or anti-coagulant drugs use

Age
From **15 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
According to balance block randomization table prepared for 300 patient with statistical software, 150 patient will be in case and the rest will be in the control group randomly.If a patient is eligible for inclusion, it will be randomly assigned to the allocation group. The patient will then receive the appropriate treatment based on the allocation group type. However, given that the patient will be described as urgent treatment if placed in the immediate treatment group and excluded if not accepted. Random allocation will be used via minimization procedure where the initial allocation treatment (first 40 cases) is based on a table of random number, subsequent allocations (from patient 41 onward) are based on a minimization protocol that has a relatively equal sample size in the two groups. The data, will be entered in SPSS software and Minim program will be employed for the minimization of the clinical data.

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 committee of Iran University of Medical Sciences
Street address
Tehran Hemmat Highway next to Milad Tower
City
Tehran
Province
Tehran
Postal code
1449614535

Approval date
2020-04-25, 1399/02/06

Ethics committee reference number
IR.IUMS.FMD.REC.1399.053

Health conditions studied

1

Description of health condition studied
Ureteral stone

ICD-10 code
N20.1

ICD-10 code description
Calculus of ureter

Primary outcomes

1

Description
Comparing the quality of life in emergency and elective ureteroscopy for treatment of ureteral stones

Timepoint
3 weeks after emergency visit

Method of measurement
Quality of life EQ_5D scale and Visual analogue Scale

Secondary outcomes

1

Description
Comparing the loss of work days in emergency and elective ureteroscopy for treatment of ureteral stones

Timepoint
3 weeks after emergency visit

Method of measurement
Ask from Patient

Intervention groups

1

Description
Intervention group:Includes patients in the immediate emergency ureteroscopic treatment who undergo ureteroscopy within 24 hours of ED visit.
Category
Treatment - Surgery

2

Description
Control group: includes patients receiving unsuccessful stone expulsive (plus analgesic) therapy for 3 to 4 weeks who will undergo ureteroscopic treatment then
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Hasheminejad hospital
Full name of responsible person
Pejman Shadpour
Street address
Haheminejad Hospital., Valinejad Alley., Valiasr Street.,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
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Seyed Abbas Motevalian
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Shadpor.p@ums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Pejman Shadpour
Position
Professor
Latest degree
Subspecialist
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
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
All data can potentially be shared after hiding patient identity
When the data will become available and for how long
18 month after article publication, data is available
To whom data/document is available
Only for researchers in universities and academic institutions
Under which criteria data/document could be used
No other condition is needed
From where data/document is obtainable
Moslem Pourakrami 00989133579530 mo.pourakrami@gmail.com
What processes are involved for a request to access data/document
After receiving an email based on the the need to access the data of his article,respond will be sent within 30 work days
Comments