

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

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

Protocol summary

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

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 pain and 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

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.,

City

Tehran

Province

Tehran

Postal code

1471319697

Phone

+98 21 81161

Email

Shadpour.p@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motevalian

Street address

Tehran Hemmat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 1021

Email

Shadpor.p@iums.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

Street address

Hasheminejad Hospital., Valinejad Street., Vali-e-asr Ave., Vanak Squ

City

Tehran

Province

Tehran

Postal code

1471319697

Phone

+98 21 8864 4485

Fax

Email

pshadpour@gmail.com

Person responsible for scientific 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
Street address
Hasheminejad Hospital., Valinejad Street., Vali-e-asr
Ave., Vanak Squ
City
Tehran
Province
Tehran
Postal code
1471319697
Phone
+98 21 8864 4485
Fax
Email
pshadpour@gmail.com

Person responsible for updating data

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
Street address
Hasheminejad Hospital., Valinejad Street., Vali-e-asr
Ave., Vanak Squ
City
Tehran
Province
Tehran
Postal code
1471319697
Phone
+98 21 8864 4485

Fax
Email
pshadpour@gmail.com

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