

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of RIRS (Retrograde Intrarenal Surgery) by Under Vision and Under Fluoroscopic Injection In patients, the candidate is RIRS

Protocol summary

Study aim

Comparison of RIRS (Retrograde Intrarenal Surgery) by Under Vision and Under Fluoroscopic Injection

Design

A clinical trial with two groups of patients: parallel, therapeutic, simple random, single blind

Settings and conduct

Prior to the study, tests will be performed on patients referred to Sina Hospital, including platelet count and white blood cell count. After the study is completed, they will be re-tested and data collected. Also, surgical complication rate will be assessed by ureteral examination after ureteral sheath removal with Rigid Toxic Ureteroscope. The infection will be assessed by examining the patients' fever rates, and finally, after six weeks of contrast-enhanced abdominal and pelvic CT scans to evaluate the success rate of surgery and after three months of IVP surgery to evaluate ureteral stenosis. Finally, statistical analysis is performed using SPSS software version 24 and the success and side effects of the two groups are compared using chi-square and Fisher tests and length of stay by independent t-test.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Referral to Sina Hospital; Patients Candidate for RIRS Stones between 1 to 2 cm in the upper, middle and pelvic cavities; stones below 2 cm in the lower calyx; Stones that have not responded to eswl treatment. Exclusion criteria: These included bleeding diseases

Intervention groups

Under Vision and Under Fluoroscopic Injection

Main outcome variables

Includes hospitalization time Sheet implantation time as well as ureteral injury as assessed by ureteroscopy after surgery and CT scan three months after surgery, and success rate in complete stone therapy, which was determined by CT scan three months later.

General information

Reason for update

Acronym

RIRS (Retrograde Intrarenal Surgery)

IRCT registration information

IRCT registration number: **IRCT20190624043991N3**

Registration date: **2019-12-31, 1398/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-31, 1398/10/10**

Update count: **0**

Registration date

2019-12-31, 1398/10/10

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8560

Email address

mkaghamir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of RIRS (Retrograde Intrarenal Surgery) by Under Vision and Under Fluoroscopic Injection In patients, the candidate is RIRS

Public title

Comparison of RIRS (Retrograde Intrarenal Surgery) by Under Vision and Under Fluoroscopic Injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have stones of between 1 and 2 cm in the middle of the upper ciliary and pelvic cavities and below 1 cm inches of lower calis. Stones that have not responded to ESWL treatment

Exclusion criteria:

Patients affected by hemorrhagic diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **118**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method used will be simple randomization. And the random number table will be used. If a number is randomly selected we will move to the right according to the preset contract and if the number even comes in The patient will be admitted to the intervention group and if the number comes in, the patient will be included in the second group (Assigning patients under Under Vision and Under Fluoroscopic Injection based on couple and individual referral number).

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients who have agreed to participate in the study will undergo RIRS in either of two ways, Under Vision or Fluoroscopic Guidance. Participants are unaware of the RIRS procedure.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee for Research in Tehran University of Medical Sciences

Street address

Room 604, Sixth Floor, medical University Tehran, Central Staff Building, Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-09-22, 1398/06/31

Ethics committee reference number

IR.TUMS.VCR.REC.1398.550

Health conditions studied

1

Description of health condition studied

Urethral stone

ICD-10 code

N21

ICD-10 code description

Calculus of lower urinary tract

Primary outcomes

1

Description

Kidney stone removal

Timepoint

Once a month

Method of measurement

CT-scan

Secondary outcomes

empty

Intervention groups

1

Description

RIRS (Retrograde Intrarenal Surgery) performed with a flexible ureterorenoscope is one of the new methods used to treat urinary stones. Intervention group: Under Vision (New method as an alternative to fluoroscopy)

Category

Treatment - Surgery

2

Description

RIRS (Retrograde Intrarenal Surgery) performed with a

flexible ureterorenoscopy is one of the new methods used to treat urinary stones. Intervention group: Under Fluoroscopic Injection: Fluoroscopic guides are a useful and effective method of determining the correct position of the needle. Fluoroscopy is a simple and accessible tool that can be used in all pain control procedures during surgery.

Category

Treatment - Surgery

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

Sina Hospital

Full name of responsible person

Dr Mohammad Kazem Aghamir

Street address

Hassan Abad

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Fax

+98 21 6634 8553

Email

mkaghamir@tums.ac.ir

Web page address

<http://urc.tums.ac.ir>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

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

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Fax

+98 21 8163 3686

Email

vcr@tums.ac.ir

Web page address

<http://vcr.tums.ac.ir/>

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

Molecular Medicine

Street address

Urology Research Center- Sina Hospital - Imam Khomeini St

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8560

Fax

+98 21 6634 8561

Email

mirzaee.scholar@gmail.com

Web page address

<https://URC@tums.ac.ir>

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Kazem Aghamir

Position

Head of Urology Research Center

Latest degree

Specialist

Other areas of specialty/work

Urology

Street addressUrology Research Center- Sina Hospital - Imam
Khomeini St**City**

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8560

Fax

+98 21 6634 8561

Email

mkaghamir@tums.ac.ir

Web page address<http://urc.tums.ac.ir>

+98 21 6634 8560

Fax

+98 21 6634 8561

Email

mirzaee.scholar@gmail.com

Web page address<https://URC@tums.ac.ir>**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 DictionaryUndecided - 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

registrant

Under which criteria data/document could be used

Re-information for the purpose of clarification

From where data/document is obtainable

Dr Seyed Mohammad Kazem Aghamir

What processes are involved for a request to access data/documentAfter the examination, the applicant will be provided with
the advice of an epidemiologist and with the
confidentiality of patient information.**Comments**

-

Person responsible for updating data**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

Molecular Medicine

Street addressUrology Research Center- Sina Hospital - Imam
Khomeini St**City**

Tehran

Province

Tehran

Postal code

1136746911

Phone