

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing mini perc outcome and RIRS in treating remaining post-PCNL stones>2 cm or Hounsfield>1000 or SSD(Skin Stone Distance)>10 cm

Protocol summary

Study aim

Comparing mini perc outcome and (RIRS) Retrograde Intrarenal Surgery) in treating remaining post-PCNL (Percutaneous Nephrolithotomy) stones>2 cm or Hounsfield>1000 or SSD(Skin Stone Distance)>10 cm

Design

A clinical trial with two groups of patients: 120 Patient, parallel, therapeutic, simple random, single-blind

Settings and conduct

A simple randomized clinical trial, single-blind(patients), 120 patients, Sina Hospital, Case Study: Patients with residual stones after PCNL over 2cm or Hounsfield over 1000 or SSD over 10cm After completing the written consent, they will be placed in one of two groups of mini perc or RIRS.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with residual stones after PCNL over 2cm 2- Hounsfield over 1000 3- SSD over 10cm Exclusion criteria: Cases that have Systemic Inflammatory Response Syndrome (SIRS).

Intervention groups

RIRS Surgery (Retrograde Intrarenal Surgery), Mini perc surgery

Main outcome variables

complications, hospitalization time, surgical time, and success rate of complete stone therapy.

General information

Reason for update

Acronym

RIRS (Retrograde Intrarenal Surgery)

IRCT registration information

IRCT registration number: **IRCT20190624043991N5**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

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

2019-09-15, 1398/06/24

Expected recruitment end date

2020-09-14, 1399/06/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing mini perc outcome and RIRS in treating remaining post-PCNL stones>2 cm or Hounsfield>1000 or SSD(Skin Stone Distance)>10 cm

Public title

Mini perc and RIRS surgery for stone treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with residual stones after PCNL over 2cm

Hounsfield over 1000 SSD over 10 cm

Exclusion criteria:

Cases that have Systemic Inflammatory Response Syndrome (SIRS).

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The selection of patients for each surgery is done by simple randomization without patient intervention. Patients were randomly assigned to Balance block randomization. For this purpose, randomization sequences were determined using the sealedenvelop.com site by assigning two groups A (intervention) and B (control), block size 4 and sample size 120.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients who have given their consent to participate in the study will be treated with SIRS or mini perc.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees in Medical Medical Research

Street address

Room 604, Sixth Floor, Central Staff Building, Tehran
University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-01-24, 1398/11/04

Ethics committee reference number

IR.TUMS.VCR.REC.1398.835

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

Treatment of urinary stones(Kidney stones)

Timepoint

One month after surgery (mini perc and RIRS)

Method of measurement

Spiral CT scan of the abdomen and pelvis, before and after surgery

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: mini perc The "mini-perc" technique of percutaneous nephrolithotomy, which uses the 14-Fr peel-away sheath, is a safe and effective modality for treating renal calculi. On the other hand, the "mini-perc" as percutaneous nephrolithotomy achieved through a sheath too small to accommodate a standard rigid nephroscope.

Category

Treatment - Surgery

2

Description

Intervention group: RIRS Retrograde Intra Renal Surgery (RIRS): In this method, a flexible urethroscope breaks the stones into crushing fragments. In this procedure, no incision is made on the patient's body and the patient can be discharged immediately after 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 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

mkaghamir@tums.ac.ir

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

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 address

Urology Research Center- Sina Hospital - Imam
Khomeini St

City

Tehran

Province

Tehran

Postal code

۱۱۳۶۷۴۶۹۱۱

Phone

+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 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

demographic information anonymously

When the data will become available and for how long

one year after publication

To whom data/document is available

Researchers working in academia, physicians, surgeons and hospitals

Under which criteria data/document could be used

Re-information for the purpose of clarification Using data by referring to the article's original Get permission from the author of the article and the presenter

From where data/document is obtainable

Sina Hospital, Urology Research Center, Head of Urology Research Center: Dr. Seyed Mohammad Kazem Aghamir 00982166348560

What processes are involved for a request to access data/document

After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.

Comments

-