

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of PCNL and RIRS surgery results for the treatment of two to four centimeters kidney stones in patients referred to Hospital

Protocol summary

Study aim

Comparison of PCNL and RIRS surgery results for the treatment of 2-4 cm kidney stones in patients referred to Hospital

Design

Using the online site sealedenvelop.com (the site for sequencing block randomization) The four blocks are randomly assigned to patients in two groups: A: PCNL, and B: RIRS. The order in which the patients are placed to operation model is provided to the technician. The study is Double blind. (Patient and surgeon) 82 patients referred to Sinai Hospital (with ethical consent) are studied. The study is an intervention, phase 3, parallel and therapeutic.

Settings and conduct

This clinical trial will be performed on 82 patients at Sina Hospital. Double blind(Patient and surgeon) Technician (importer of patients in each group based on random blocks) Random blocks, four blocks randomly from patients A: PCNL, B: RIRS. 21 quadruple blocks are made which are placed in separate envelopes. Randomized blocks are given to a technician. After the patient enters, the technician performs the intervention by opening each envelope regarding the intervention method (A or B) for the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with BMI = 30 to BMI = 40 with kidney stones 2 to 4 cm and age range 18 to 80 years
Exclusion criteria: Age under 18 or above 80, BMI above 40 or below 30, kidney stone size above 4 or below 2 cm
Cases that have Systemic Inflammatory Response Syndrome (SIRS) uncorrected coagulopathy untreated urinary tract infection

Intervention groups

(Percutaneous Nephrolithotomy) PCNL operation : Skin tunneling, without surgical incision (Retrograde intrarenal surgery) RIRS operation: A tube enters through the urethra

Main outcome variables

The treatment of stones

General information

Reason for update

Acronym

Percutaneous Nephrolithotomy (PCNL)- Retrograde intrarenal surgery (RIRS)

IRCT registration information

IRCT registration number: **IRCT20190624043991N9**

Registration date: **2020-09-13, 1399/06/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-13, 1399/06/23**

Update count: **0**

Registration date

2020-09-13, 1399/06/23

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6634 8560

Email address

mkaghamir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2020-11-30, 1399/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of PCNL and RIRS surgery results for the treatment of two to four centimeters kidney stones in patients referred to Hospital

Public title
Comparison of PCNL and RIRS surgery in the treatment of two to four centimeters kidney stones

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patient with BMI = 30 to BMI = 40 with kidney stones 2 to 4 cm and age range 18 to 80 years
Exclusion criteria:
Age under 18 or above 80, BMI above 40 or below 30, kidney stone size above 4 or below 2 cm Cases that have Systemic Inflammatory Response Syndrome (SIRS) uncorrected coagulopathy untreated urinary tract infection

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **82**

Randomization (investigator's opinion)
Randomized

Randomization description
The present study is a double-blind randomized clinical trial. For randomization, the blanced block randomization method is used to generate four blocks. Intervention group A and control group B have been determined.According to the randomization method, we expect the two groups to differ by a maximum of 2 people in terms of the number of people assigned. After the methodologist prepares the randomization sequence using the sealdenvelop online site, the generated sequence will be made available to a technician outside the research team.Quadruple blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected and the type of patient group is informed to the research team through a trained technician.The patient is placed in RIRS or PCNL treatment group based on the randomly selected envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients who have given their consent to participate in the study and Therapist To perform the blinding process, envelopes related to the type of intervention are

provided only to the technician. The physician is not informed of the type of intervention (RIRS or PCNL) (to avoid bias).

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
2020-06-28, 1399/04/08

Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1399.013

Health conditions studied

1

Description of health condition studied
kidney stones

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

Intervention group: Group 1: PCNL treated

Category

Treatment - Surgery

2

Description

Intervention group: Group 2: RIRS treated

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr seyed mohammad kazaem aghamir mohammadali

Street address

Hassan Abad

City

Tehran

Province

Tehran

Postal code

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Email

mkaghamir@tums.ac.ir

Web page address

http://sinahospital.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

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Web page address

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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

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Urology Research Center- Sina Hospital - Imam Khomeini St

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seyed Mohammad Kazem Aghamir

Position

Head of urology research center department

Latest degree

Subspecialist

Other areas of specialty/work

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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

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

-

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

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