

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the success rate of the percutaneous nephrolithotomy for nonopac kidney stones with two methods; fluoroscopic vs ultrasound guided : a randomized clinical trial

Protocol summary

Study aim

A randomized clinical trial to compare the success rate of non opacity kidney stones surgery with two fluoroscopic and ultrasound methods

Design

Two arm parallel group randomized trial, tree blinded, sample size is 42

Settings and conduct

1-The study is being conducted at Bamonar Hospital in Kerman Province. 2-Participants and outcome assessors and data analysts were not aware of either patient's ultrasound or fluoroscopy status.Each patient is randomly assigned to a group after anesthesia.The outcome assessor and analysts have access to all data except the patient placement group.

Participants/Inclusion and exclusion criteria

Inclusion criteria:non opacity kidney stones;All patients with staghorn,calyceal or pelvic stone who are candidate for percutaneous nephrolithotomy. non-inclusion criteria:Under 12 years of age;uncorrected coagulation disorder;active urinary tract infection.

Intervention groups

Intervention group 1:sonography:With the guidance of ultrasound in the transverse section, the Shiba needle enters the pelvis. Intervention group 2:fluoroscopy:After retrograde injection of the contrast and observation of pelvis, the shiba needle is inserted.

Main outcome variables

Residual stones; surgical complications; surgical success

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160416027426N3**
Registration date: **2020-04-24, 1399/02/05**

Registration timing: **prospective**

Last update: **2020-04-24, 1399/02/05**

Update count: **0**

Registration date

2020-04-24, 1399/02/05

Registrant information

Name

Hamid Pakmanesh

Name of organization / entity

Department of urology, Kerman University of Medical sciences (KMU)

Country

Iran (Islamic Republic of)

Phone

+98 34 3244 8777

Email address

h_pakmanesh@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the success rate of the percutaneous nephrolithotomy for nonopac kidney stones with two methods; fluoroscopic vs ultrasound guided : a

randomized clinical trial

Public title

Comparison between sonographic and flourosopic guided PCNL in renal stone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Non opacity kidney stones All patient with staghorn, calyceal or pelvic stone who are candidate for percutaneous nephrolithotomy (PCNL)

Exclusion criteria:

Under 12 years of age uncorrected coagulation disorder active urinary tract infection

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple. Randomization tool: magic hat statistical software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants and outcome assessors and data analysts were not aware of either patient's ultrasound or fluoroscopy status.Each patient is randomly assigned to a group after anesthesia.The outcome assessor and analysts have access to all data except the patient placement group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

At the beginning of Ebne Sina street, At the beginning of Jahad street, Somayeh intersection

City

Kerman

Province

Kerman

Postal code

7618778584

Approval date

2020-02-29, 1398/12/10

Ethics committee reference number

IR.KMU.REC.1398.080

Health conditions studied

1

Description of health condition studied

Renal stone

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

Residual stone

Timepoint

after surgery during one month period

Method of measurement

physician visit based on computed tomography scan (CT scan)

Secondary outcomes

1

Description

Surgical complications

Timepoint

At the time of hospitalization after surgery

Method of measurement

physician visit based on Clavien classification

Intervention groups

1

Description

Sonography group:Under the guidance of ultrasound in the transverse section,the Shiba needle enters the pelvis, and other stages of percutaneous nephrolithotomy are performed.

Category

Treatment - Surgery

2

Description

Fluoroscopic group:After retrograde injection of the contrast and observation of pelvis, the Shiba needle is inserted and other stages of percutaneous nephrolithotomy are performed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman Shahid Bahonar hospital

Full name of responsible person

Siavash Vejdani

Street address

Bahrololum street

City

Kerman

Province

Kerman

Postal code

7618778584

Phone

+98 34 3425 4828

Email

Siavj@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

Street address

Tahmasab Abad intersection

City

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Province

Kerman

Postal code

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Email

siavj@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Dr Siavash Vejdani

Position

Resident in training in Urology

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of urology, Kerman university of medical sciences (KMU)

Full name of responsible person

Dr Hamid Pakmanesh

Position

Assistant professor, Endourologist

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Siavash Vejdani

Position

Assistant of urology

Latest degree

Specialist

Other areas of specialty/work

Urology

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Email

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes can be shared

When the data will become available and for how long

Access period 6 months after the results are published

To whom data/document is available

Everyone

Under which criteria data/document could be used

Used in a similar study

From where data/document is obtainable

Project general officer: Siavash Vejdani, Cellphone number: 09363721535; Email: siavj@yahoo.com

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

Send e-mail to the given email address and send the full details of the new study

Comments