Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of using a newly designed splitted side Amplatz sheath and conventional Amplatz sheath in patients undergoing percutaneous nephrolithotomy in terms of surgical outcomes and complications

Protocol summary

Study aim

To find the most effective and the safest device for PCNL operation

Design

In this randomized interventional study, we want to gather 100 patients with renal stone and aged more than 18 years who refer to the Stone Clinic of Shahid Faghihi Hospital. We will randomly categorize our patients into control and intervention group. Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct

In this randomized interventional study, we want to gather 100 patients with renal stone and aged more than 18 years who refer to the Stone Clinic of Shahid Faghihi Hospital. Patients will be informed completely about the new splitted side Amplatz sheath and the old method and informed consent will be obtained. We will randomly categorize our patients into control and intervention group. For our control group PCNL will be done with conventional Amplatz sheath while for intervention group a new splitted side Amplatz sheath will be used. Patients with single kidney and abnomrmal kidney function will be excluded from our study. All procedures will be done by a single surgeon and under the general anesthesia. Routine laboratory tests will be recorded preoperatively. One gram Intravenous ceftriaxone will be administrated preoperatively as prophylactic antibiotic and it will be continued (1g twice a day) for 48 hours postoperatively.]n both group Abdominal spiral CT scan without contrast will be performed for exclusion of significant residual renal and ureteric stones. Ureteric and foley catheter will be removed 24 hours postoperatively and nephrostomy tube will be removed 48 hours postoperatively if there is no obstructive stone particle. Ultrasound scan will be done for all patients for evaluation of perirenal fluid collection. Renal function tests and complete blood cell count will be recorded postoperatively. All patients will have regular follow-up with sonography, and laboratory exams in the Stone Clinic.

Participants/Inclusion and exclusion criteria

Patients with renal stone more than 18 years old who wants to go under PCNL will be included in this study and those with single kidney and abnormal renal function will be excluded.

Intervention groups

The intervention group will be gone under PCNL by using a new splitted Amplatz sheath while the control group will be operated by the conventional PCNL technique.

Main outcome variables

Particle extraction time; Operation time; Post-operative fever; Residual stone size>5mm, Blood transfusion; Perirenal fluid collection; Mean hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171126037628N1**
Registration date: **2018-03-05, 1396/12/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-05, 1396/12/14**
Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Abdolreza Haghpanah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 1563

Email address
haghpanahr@sums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-20, 1396/12/01
Expected recruitment end date
2018-06-22, 1397/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of using a newly designed splitted side Amplatz sheath and conventional Amplatz sheath in patients undergoing percutaneous nephrolithotomy in terms of surgical outcomes and complications

Public title
Using a new splitted Amplatz sheath in PCNL operation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients above 18 years old with renal stone who wants to go under PCNL
Exclusion criteria:
solitary kidney abnormal renal function.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
We randomly gathered our study samples from Patients above 18 years old with renal stone who wants to go under PCNL. Sample size is calculated as 100 patients based on a Type I error of 5%, statistical power 80%. Patients will be divided randomly into two groups, each containing 50 members by blocking randomization.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients will be informed well about both technique though will not know by which method they will be operated. Also different physician will follow patients who will not know the type of operation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Province
Fars
Postal code
14336 - 71348
Approval date
2018-02-07, 1396/11/18
Ethics committee reference number
IR.SUMS.REC.1396.168

Health conditions studied

1

Description of health condition studied
renal stone
ICD-10 code
N20
ICD-10 code description
Calculus of kidney and ureter

Primary outcomes

1

Description
Operation time
Timepoint
one time after the procedure
Method of measurement
by lessen the time of initiation from end of surgery

2

Description
Need for blood transfusion
Timepoint
during the surgery and admission days
Method of measurement
By reading operation and nursing note

3

Description
Perirenal fluid collection
Timepoint
after surgery
Method of measurement
Sonography

4

Description
addmission duration
Timepoint
After admission
Method of measurement
Reading patient document

5

Description
Post operation fever
Timepoint
after surgery
Method of measurement
thermometer

6

Description
Residual stone size>5mm
Timepoint
One time after operation
Method of measurement
CT scan and Songography post operation

7

Description
Particle extraction time
Timepoint
Once during operation
Method of measurement
Clock

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Renal stone patients older than 18 years without exclusion criteria and will be gone under the PCNL surgery with newly designed splitted side Amplatz sheath
Category
Treatment - Surgery

2

Description
Control group: Renal stone patients older than 18 years without exclusion criteria and will be gone under the PCNL surgery with conventional Amplatz sheath
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Abdolreza Haghpanah
Street address
No. 7134844119, Shahid Faghihi hospital, Zand Ave, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3628 1563
Fax
+98 71 3628 1563
Email
haghpanahr@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Seyed Basir Hashemi
Street address
No. 7134814336 , Shiraz University of medical sciences central tower, Palestine Street, Zand Avenue, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3235 7282
Email
hashemib@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Abdolreza Haghpanah

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Urology

Street address
No. 7134844119, Shahid Faghihi hospital, Zand Ave, Shiraz, Iran

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Person responsible for scientific inquiries

Contact

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Fax
+98 71 3628 1563

Email
haghpanahr@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Abdolreza Haghpanah

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City
Shiraz

Province
Fars

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
As long as we want to share the result of our study with other researchers we will write a paper that contain all the information about our study such as method, analysis, and results. Also if the journal or other researchers ask us to share our patients' data and their informed consent we are ready to share them.

When the data will become available and for how long
while our paper published

To whom data/document is available
All the researchers that prove they are researchers

Under which criteria data/document could be used

Our data only can be used in other researches

From where data/document is obtainable

By sending a request to first or corresponding author's email

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

Researcher who needs our data must introduce his/her completely (including his/her name and family name, occupation, place of work, address) and introduce us two to three of his/her previous studies along with the request email

Comments