Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Randomized Clinical trail comparing Balloon dilation versus Amplatz dilation for ultrasound-guided percutaneous nephrolithotomy (PCNL)

Protocol summary

Summary

(1) Objectives: In this study, we will compare success rate and complications of two different methods of tract dilatation for totally- ultrasonographically guided PCNL including balloon dilator and Amplatz dilator. (2) Design: double blind randomized clinical trial (3) Setting and conduct: In all patients, after access to the desired calyx with Chiba needle, a 0.035-inch J-tip guide wire will be placed in the system. Then the tract will be dilated up to 11 French using serial dilators. In this step in the first study group, Amplatz dilator will be used for tract dilatation. In the other study group, the tract will be dilated using balloon dilatator. One of the operating room stuffs will blindly record the time spent for each step of the surgery separately. A physician will blindly record any complication during hospital stay and follow-up based on Clavien classification. (4) Participants: 60 cases of totally-ultrasonographically guided PCNL will be randomly assigned in two study groups. All patients including patients with staghorn, calyceal (in one or two calyces) or single pelvic stone who are candidate for PCNL are included. Patients with scattered stones in different calyxes will be excluded. (5) Intervention: In the first group, dilatation will be performed using Amplatz dilator but in the second group, balloon dilator will be used. (6) Main outcome measures: surgery duration, complications and success rate

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041727426N2**
Registration date: **2016-05-25, 1395/03/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-05-25, 1395/03/05

Registrant information

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Recruitment status

Recruitment complete

Funding source

Kerman university of medical sciences (KMU)

Expected recruitment start date

2016-06-04, 1395/03/15

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized Clinical trail comparing Balloon dilation versus Amplatz dilation for ultrasound-guided percutaneous nephrolithotomy (PCNL)

Public title

Balloon dilation versus Amplatz dilation for ultrasound-guided percutaneous nephrolithotomy (PCNL)

Purpose

Treatment

Inclusion/Exclusion criteria
inclusion criteria: All patients including patients with staghorn; calyceal (in one or two calyces) or single pelvic stone who are candidate for PCNL are included. exclusion criteria: Patients with scattered stones in different calyxes will be excluded.
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
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
Ebne sina st, Jahad st, Somayeh cross
City
Kerman
Postal code
Approval date
2016-01-06, 1394/10/16
Ethics committee reference number
IR.kmu.REC.1394.446

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
surgical complication
Timepoint
after surgery during one month period
Method of measurement
physician visit based on Clavien classification

2

Description
surgery duration
Timepoint
during surgery
Method of measurement
hour

Secondary outcomes

1

Description
residual stone
Timepoint
the day after surgery
Method of measurement
sonography and radiology

Intervention groups

1

Description
Amplatz group: In all patients, after access to the desired calyx with Chiba needle, a 0.035-inch J-tip guide wire will be placed in the system. Then the tract will be dilated up to 11 French using serial dilators. In this step in the first study group, Amplatz dilator will be used for tract dilatation.single use Amplatz and sheath from Boston scientific corporation will be used.
Category
Treatment - Surgery

2

Description
Baloon group: In all patients, after access to the desired calyx with Chiba needle, a 0.035-inch J-tip guide wire will be placed in the system. Then the tract will be dilated up to 11 French using serial dilators.then In the second study group, the tract will be dilated using balloon dilatator. Baloon dilator set with sheath 28 or 30 French sized from Boston Scientific corporation will be used.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Bahonar Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman university of medical sciaences
Full name of responsible person
Dr Abbas Pardakhti
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kerman
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 sciaences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty