

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Randomized Clinical trial 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 dilator. 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 calyces 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

Name

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Name of organization / entity

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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 calyces 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

Ms. Zandi

Street address

Shahid Qarani St.

City

Kerman

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

Tahmasb abad cross

City

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 sciences

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

Contact

Name of organization / entity

Kerman university of medical sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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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