

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of operative time and results in patients who undergo percutaneous nephrolithotomy with and without splitting amplatz sheath

Protocol summary

2013-06-26, 1392/04/05

Summary

The objective of the present study is to determine the impact of splitting amplatz sheath on the operative time. Design: First for the pilot study, 10 patients were chosen and with their full consent, they underwent Percutaneous Nephrolithotomy with and without splitting Amplatz sheath. After assessing and making sure of the primary results, a not blinded randomized clinical trial was designed. Method: Patients are randomly divided into two groups of 36. The first group undergoes Percutaneous Nephrolithotomy with longitudinal split in Amplatz sheath, while for the second group, Amplatz sheath is kept intact. Operative time, fluoroscopic time, hemoglobin decline and residual stone will be compared between the two groups. Inclusion criteria: Patients who are candidate for Percutaneous Nephrolithotomy with kidney stones larger than 2cm in diameter or stones resistant to extracorporeal shock wave lithotripsy (ESWL). Exclusion criteria: Patients with multiple stones, cardiac problems, liver or renal failure and supine position. Intervention: The first group undergoes Percutaneous Nephrolithotomy with longitudinal split in Amplatz sheath, while for the other group Amplatz sheath is kept intact. Main outcome measures (variables): Operative time, fluoroscopic time, and residual stone.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111187457N7**

Registration date: **2013-06-26, 1392/04/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Shabnam Golshan

Name of organization / entity

Urology and Nephrology Research Center (UNRC)

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 7222

Email address

shgolshan@unrc.ir

Recruitment status

Recruitment complete

Funding source

This project will be supported by Urology and nephrology research center related to Shahid Behshti university of Medical sciences.

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of operative time and results in patients who undergo percutaneous nephrolithotomy with and without splitting amplatz sheath

Public title

The impact of longitudinal splitting of Amplatz sheath on the results of Percutaneous Nephrolithotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who are candidate for Percutaneous Nephrolithotomy with kidney stones larger than 2cm in diameter or stones resistant to extracorporeal shock wave lithotripsy (ESWL). Exclusion criteria: Patients with multiple stones, cardiac problems, liver or renal failure and supine position.

Age

From **10 years** old to **80 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sampling method is based on Archive number. For even Archive numbers, amplatz sheath was kept intact and for odd numbers, amplatz sheath was split.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of medical sciences ethics committee

Street address

No.103, 9th Boostan St., Pasdaran Ave.,Tehran

City

Tehran

Postal code

1666677951

Approval date

2013-03-12, 1391/12/22

Ethics committee reference number

الف/م/ت/17

Health conditions studied

1

Description of health condition studied

kidney stone

ICD-10 code

N20.0

ICD-10 code description

NEPHROLITHIASIS nos

Primary outcomes

1

Description

duration of surgery

Timepoint

During surgery

Method of measurement

Length of time between prone position to supine position

2

Description

Duration of Fluoroscopy

Timepoint

during surgery

Method of measurement

Fluoroscope recordings

3

Description

residual stone

Timepoint

one day after surgery

Method of measurement

ultrasonography and plain abdominal x-ray

Secondary outcomes

1

Description

Size of primary stone

Timepoint

Before surgery

Method of measurement

The longest longitudinal side x the longest width side (cm²)

2

Description

Hemoglobin

Timepoint

one day before surgery, the day after surgery and at discharge time

Method of measurement

Laboratory test (CBC)

Intervention groups

1

Description

Control group: 36 patients undergo Percutaneous

Nephrolithotomy using 30 French(f.) Amplatz sheath without splitting.

Category

Treatment - Surgery

2

Description

intervention group:36 patients undergo Percutaneous Nephrolithotomy using 30 French (f.) Amplatz sheath with splitting

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Labbafinejad Medical Center

Full name of responsible person

Ali Tabibi

Street address

No. 99.,9th Boostan St. ,Pasdaran Ave.,Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research, Shahid Beheshti university of medical sciences

Full name of responsible person

Shahid Beheshti University of medical sciences

Street address

Shahid Arabi st.,Yaman st.,Shahid Chamran Highway,Tehran

City

Tehran

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, Shahid Beheshti 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

Shahid Labbafinejad Medical Center

Full name of responsible person

Dr. Amir Reza Abedi

Position

Urologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Labbafinejad Medical Center

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