Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

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

2013-06-26, 1392/04/05

Registrant information

Name
Shabnam Golshan
Name of organization / entity
Urology and Nephrology Research Center (UNRC)
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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
17/الف/م/ت

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 (cm^2)

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

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Full name of responsible person

Amir Reza Abedi

Position

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Other areas of specialty/work

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Web page address

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