

# 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 (cm<sup>2</sup>)

### 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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**Position**

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**Email**  
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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*