

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 2026

### A comparison of the nephrostomy tract dilatation between balloon catheter and telescopic technique for percutaneous nephrolithotomy

#### Protocol summary

##### Summary

Our aim in this study is to compare nephrostomy tract dilatation between balloon catheter and telescopic technique for percutaneous nephrolithotomy. The key inclusion criteria are to be 18 to 70 years old; to have indication for percutaneous nephrolithotomy and the key exclusion criteria is to have a history of flank surgery and multiple nephrostomy tracts. In a randomized single blinded unicentral study patients administered in Emam Reza hospital, Tabriz, Iran and candidate for percutaneous nephrolithotomy will be assigned to receive one of these treatments: in group 1 a 10 to 15 cm length and 10 to 12 mm diameter balloon would be used to dilate the tract and then using a nephroscope and a lithotomy set stone would be broken and extracted from the tract; in group 2 using telescopic technique 8 metal dilators up to Fr27 diameter would be used to dilate the tract and a nephroscope and lithotomy set to break the stones and extract from the tract. To detect any probable hemorrhage hemoglobin before, 6 and 24 hours after the operation will be checked for all the patients and to detect urine leak or urinoma a sonography and KUB would be performed a day after the operation to compare the results.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201205299904N1**

Registration date: **2012-06-11, 1391/03/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-06-11, 1391/03/22

#### Registrant information

##### Name

Mohsen Amjadi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 411584153

##### Email address

amjadm@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tabriz University of Medical Sciences

#### Expected recruitment start date

2012-05-21, 1391/03/01

#### Expected recruitment end date

2012-11-21, 1391/09/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A comparison of the nephrostomy tract dilatation between balloon catheter and telescopic technique for percutaneous nephrolithotomy

#### Public title

Comparison of nephrostomy tract dilatation using balloon catheter or telescopic technique

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 70 years old and having indication for percutaneous nephrolithotomy.  
Exclusion criteria: history of flank surgery and multiple

nephrostomy tracts and any systemic disease which might affect treatment outcome.

#### Age

From **18 years** old to **70 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical Committee of Tabriz University of Medical Sciences

##### Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Square

##### City

Tabriz

##### Postal code

#### Approval date

2012-05-01, 1391/02/12

#### Ethics committee reference number

5/41396

## Health conditions studied

### 1

#### Description of health condition studied

Nephrolithiasis

#### ICD-10 code

N20.0

#### ICD-10 code description

Calculus of kidney

## Primary outcomes

### 1

#### Description

Blood hemoglobin level

#### Timepoint

Before, 6 and 24 hours after the operation

#### Method of measurement

Labratory (mg/dl)

### 2

#### Description

Number of residual stones

#### Timepoint

One day after the operation

#### Method of measurement

Using sonography and KUB

### 3

#### Description

Urine leak

#### Timepoint

6 hours after the operation

#### Method of measurement

Sonography

### 4

#### Description

Urinoma

#### Timepoint

6 hrs after the operation

#### Method of measurement

Sonography

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

For ballon group: to dialate the tract a 10 to 15 cm length and 10 to 12 mm diameter balloon would be used. Then using a nephroscope and nephrolithotomy set stones would be broken and extracted from the tract.

#### Category

Treatment - Surgery

### 2

#### Description

For telescopic group: 8 metal dialators up to Fr27 diameter would be used to dialate the tract and a nephroscope and lithotomy set to break the stones and extract from the tract

#### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Imam Reza hospital

**Full name of responsible person**

Arash Nouri

**Street address**

Imam Reza hospital, Golgasht st.

**City**

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Alireza Ostad Rahimi

**Street address**

Vce chancellor for research, Tabriz University of Medical Sciences, Daneshgah square

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Arash Nouri

**Position**

MD, Urology resident

**Other areas of specialty/work**

**Street address**

Urology ward, Imam Reza hospital, Golgasht st.

**City**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohsen Amjadi

**Position**

Associate professor/ Urologist

**Other areas of specialty/work**

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**Fax**

**Email**

amjadm@tbzmed.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Arash Nouri

**Position**

MD, Urology resident

**Other areas of specialty/work**

**Street address**

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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*