

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)

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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

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Person responsible for scientific inquiries

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Tabriz University of Medical Sciences

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Mohsen Amjadi

Position

Associate professor/ Urologist

Other areas of specialty/work

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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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Phone

Fax

Email

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