

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of one step tract dilatation for percutaneous nephrolithotripsy in patient with and without kidney operation.

Protocol summary

Summary

The objective of this study was to assess the feasibility of one-stage acute dilation of the nephrostomy tract with a 30F Amplatz dilator in patients who are candidate for percutaneous nephrolithotomy (PCNL), regardless of whether there is a previous renal scar to make the procedure less time consuming and more cost effective. One-stage tract dilation for PCNL was done in 100 patients with age more than 16 and kidney stone greater than 2 cm who had been referred to Labafinejad Hospital and were candidates for percutaneous nephrolithotomy (PCNL). Access time and radiation exposure time during access were compared in patients with and without history of ipsilateral open stone surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803191267N15**

Registration date: **2009-08-24, 1388/06/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-08-24, 1388/06/02

Registrant information

Name

Mojgan Borgheie

Name of organization / entity

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 7222

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Recruitment status

Recruitment complete

Funding source

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.R.
Iran

Expected recruitment start date

2007-03-21, 1386/01/01

Expected recruitment end date

2009-03-21, 1388/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of one step tract dilatation for percutaneous nephrolithotripsy in patient with and without kidney operation.

Public title

Comparison of one step tract dilatation for percutaneous nephrolithotripsy in patient with and without kidney operation.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 16 years, kidney stone greater than 2 cm Exclusion criteria: Presence of UTI, pyonephrosis, or coagulation disorder, no allowance for general anesthesia

Age

From **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.

Street address

UNRC, No.101,9th Boostan St., Pasdaran Ave.,
Tehran, I.R. Iran

City

Tehran

Postal code

1666677951

Approval date

2005-02-09, 1383/11/21

Ethics committee reference number

71

Health conditions studied**1****Description of health condition studied**

kidney stone

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes**1****Description**

Access time

Timepoint

during surgery

Method of measurement

Time of access in minutes

Secondary outcomes**1****Description**

X-RAY exposure time

Timepoint

During surgery

Method of measurement

ARM-C

2**Description**

Bleeding complications

Timepoint

during surgery

Method of measurement

Bleeding volume in cc

Intervention groups**1****Description**

Access in patients under percutaneous nephrolithotripsy
and with or without previous scar

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Labafi Nejad Hospital

Full name of responsible person

Dr Seyed Amir Mohsen Ziaee

Street address

Labafi Nejad Hospital, 9th Boostan St., Pasdaran Ave.,
Tehran, I.R. Iran

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran,

Full name of responsible person

Shabnam Golshan

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UNRC, No.101, Boostan 9th St., Pasdaran Ave.,
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran,

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

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.R.

Full name of responsible person

Dr Seyed Amirmohsen Ziaee

Position

Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Full name of responsible person

Dr Mozghan Borgheie

Position

MD

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