

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparing efficacy and safety of conventional and totally tubeless percutaneous nephrolithotomy in under 14 year-old patients; a clinical trial

Protocol summary

Summary

To assess the outcome and safety of the totally tubeless percutaneous nephrolithotomy (PCNL) in compare with standard PCNL in the children under 14 years old. Twenty three patients with upper pole renal stones were enrolled in a prospective randomized clinical trial during July 2010 to Jan 2012. The inclusion criteria were patient age less than 14 years old; existence of stone size >2.5 cm; stone resistant to the extracorporeal shockwave lithotripsy (SWL); furthermore, exclusion criteria were serious bleeding; perforation in the collecting system during the operation; kidney anomalies; renal failure on admission. The patients were divided into two groups. Totally tubeless percutaneous nephrolithotomy was performed on one group while, patients in another group underwent standard procedure. The incidence of complications, hospital stay, transfusion rate, stone free rate and analgesic use were compared between the two groups during a 1-month study period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110017675N1**

Registration date: **2011-10-08, 1390/07/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-08, 1390/07/16

Registrant information

Name

Mehdi Aloosh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2010-07-01, 1389/04/10

Expected recruitment end date

2011-12-31, 1390/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy and safety of conventional and totally tubeless percutaneous nephrolithotomy in under 14 year-old patients; a clinical trial

Public title

Comparing efficacy and safety of conventional and totally tubeless percutaneous nephrolithotomy in under 14 year-old patients; a clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria were patient age less than 14 years old; the existence of stone size >2.5 cm; stone resistant to extracorporeal shockwave lithotripsy (SWL). The

exclusion criteria were serious bleeding; perforation in the collecting system during the operation; kidney anomalies; renal failure on admission.

Age

To **14 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

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

Tehran University of Medical Sciences' ethical committee

Street address

Tehran University of Medical Sciences, Enghelab St.

City

Tehran

Postal code

Approval date

2011-09-10, 1390/06/19

Ethics committee reference number

14418

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

postoperative analgesic requirement

Timepoint

after surgery till discharge

Method of measurement

mg of morphine use

2

Description

hospitalization period

Timepoint

after surgery till discharge

Method of measurement

days of hospitalization

Secondary outcomes

1

Description

operation time

Timepoint

time of surgery

Method of measurement

minutes of surgery

2

Description

Hemoglobin changes

Timepoint

during surgery till discharge

Method of measurement

mg/dl of Hemoglobin

3

Description

need to re-operation

Timepoint

after surgery, 1 week and 1 month later

Method of measurement

need to re-operation

Intervention groups

1

Description

intervention: Totally tubeless percutaneous nephrolithotomy

Category

Treatment - Surgery

2

Description

control: standard percutaneous nephrolithotomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology department, Sina hospital

Full name of responsible person

Alborz Salavati

Street address

Urology department, Sina hospital, Hasan abad Sq.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Fotoohi

Street address

4th Floor, Central Building of Tehran University of Medical Sciences, Ghods St, Keshavarz Av.

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, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mehdi Aloosh

Position

Researcher /MD

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

Associated Professor/ MD

Other areas of specialty/work

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Person responsible for updating data

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Position

urology resident

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