Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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, Centeral 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
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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