Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The safety and efficacy of Extracorporeal Shockwave Lithotripsy versus Transureteral Lithotripsy for the treatment of pediatric lower ureteral stones: a multicentric randomized clinical trial

Protocol summary

Summary

In this study, we are intending to compare two surgical methods (ESWL and TUL) for the treatment of pediatric lower ureteral stones. 50 children below the age of 13 years with lower urethral stones and without ureteral anomaly or untreated coagulopathy who were referred to Shahid Labbafinejad Hospital will participate in this study to undergo Extracorporeal Shockwave Lithotripsy or Transurethral Lithotripsy through a multicentre randomized clinical trial. We compare two interventions kinds of surgery regarding becoming stone-free (effective factors on the treatment outcome such as size, number, location, and density of stone), the need for repeating the treatment, rate of minor complications (including inserting ureteral stents, nephrostomy,....), the rate of minor surgical complications such as pain, hematuria, UTI, steinstrasse, and major complications (ureteral perforation, detachment or stenosis, septicemia, non-functional kidney), and the patient's and family's satisfaction. Patients are followed up through physical examination, IVP and sonography up to 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138707021267N1**
Registration date: **2009-08-30, 1388/06/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-08-30, 1388/06/08

Registrant information

Name

Mojgan Borgheie

Name of organization / entity

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

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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

2008-10-06, 1387/07/15

Expected recruitment end date

2010-02-18, 1388/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The safety and efficacy of Extracorporeal Shockwave Lithotripsy versus Transureteral Lithotripsy for the treatment of pediatric lower ureteral stones: a multicentric randomized clinical trial

Public title

The safety and efficacy of Extracorporeal Shockwave Lithotripsy versus Transureteral Lithotripsy for the treatment of pediatric lower ureteral stones: a multicentric randomized clinical trial

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age less than 13 years, presence of lower urethral stones Exclusion criteria: History of previous urethral surgery, Ureteral anomaly, UTI, Untreated coagulopathy
Age
From **1 year** old to **13 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 (SBMU)
Street address
Urology and Nephrology Research center, No44, 9th Boostan St., Pasdaran Ave.,Tehran, I.R.Iran
City
Tehran
Postal code
1666677951
Approval date
2008-02-05, 1386/11/16
Ethics committee reference number
88

Health conditions studied

1

Description of health condition studied
lower ureteral stone
ICD-10 code
N20.1
ICD-10 code description
Calculus of ureter

Primary outcomes

1

Description
pain after surgery
Timepoint
up to 3 months
Method of measurement
Asking the patient

2

Description
hematuria
Timepoint
up to 3 months
Method of measurement
Asking the patient

3

Description
incidence of urinary tract infection
Timepoint
up to 3 months
Method of measurement
urinary culture

Secondary outcomes

1

Description
perforation of ureter
Timepoint
After surgery
Method of measurement
sonography and IVP

2

Description
stenosis of ureter
Timepoint
After surgery
Method of measurement
sonography and IVP

3

Description
incidence of septicemia
Timepoint
After surgery
Method of measurement
Blood culture

4

Description
Incidence of non-functional kidney
Timepoint
After surgery
Method of measurement
sonography and IVP

Intervention groups

1

Description
ESWL
Category
Treatment - Other

2

Description
TUL
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Labbafinejad Medical Center
Full name of responsible person
Dr. Sohrabpoor
Street address
9th Boostan, Pasdaran Ave.,Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology and Nephrology Research center (SBMU)
Full name of responsible person
Shabnam Golshan
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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 (SBMU)
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
Full name of responsible person
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Position
Resident of urology
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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General Physician

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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