

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Medical 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

Street address

Urology and Nephrology Research center, No44, 9th Boostan, Pasdaran Ave.,Tehran

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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

Dr. Samad Zare

Position

Resident of urology

Other areas of specialty/work**Street address**

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professor

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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