

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The extracorporeal shock wave lithotripsy efficacy in stone-free rate in pediatric urolithiasis (up to 15 Years)

Protocol summary

Study aim

The extracorporeal shock wave lithotripsy efficacy in stone-free rate in pediatric urolithiasis (up to 15 Years old)

Design

patients under the age of 15 with urolithiasis and underwent (ESWL) were included in the study .

Settings and conduct

After Extracorporeal shock wave lithotripsy (ESWL) , children are subjected to ultrasound again within 48 hours, 14 days and two months later, and are followed up in terms of stone clearance and complications. Also, two weeks after ESWL, biochemical tests are also performed.

Participants/Inclusion and exclusion criteria

All children under 15 years old with kidney stones But patients with stones larger than 2 cm, patients with a history of previous stone surgery are not included in the study

Intervention groups

After Extracorporeal shock wave lithotripsy (ESWL) , children are subjected to ultrasound again within 48 hours, 14 days and two months later, and are followed up in terms of stone clearance and complications. Also, two weeks after ESWL, biochemical tests are also performed. In the 1st group of patients 7 years or less, the average number of stone breaking sessions was 1.16, in the second group, the average number of stone breaking sessions was 2.97. Extracorporeal lithotripsy is more effective for younger children and the number of sessions is less, and it is a safe and effective method for treating urinary system stones up to 1 cm in children.

Main outcome variables

Stone location, stone size, number of stones, frequency of extracorporeal shockwave lithotripsy (ESWL)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241224064151N1**

Registration date: **2025-02-12, 1403/11/24**

Registration timing: **retrospective**

Last update: **2025-02-12, 1403/11/24**

Update count: **0**

Registration date

2025-02-12, 1403/11/24

Registrant information

Name

Behrooz Shirzad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2360 2139

Email address

behroozsh0457@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The extracorporeal shock wave lithotripsy efficacy in stone-free rate in pediatric urolithiasis (up to 15 Years)

Public title

Investigating the effect of extracorporeal shockwave lithotripsy (ESWL) in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

children under 15 y/o with renal stone

Exclusion criteria:

Patient with renal stone > 2cm patient with h/o renal stone open surgery Genitourinary system abnormalities Staghorn stones

Age

To 15 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 55

Randomization (investigator's opinion)

N/A

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

Ethics committee of Shahid Beheshti university of Medical Sciences

Street address

Arabi Street (Parvaneh), Student Blvd., Volenjak, Tehran

City

Tehran

Province

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Postal code

1478798771

Approval date

2024-12-03, 1403/09/13

Ethics committee reference number

IR.SBMU.MSP.REC.1403.532

Health conditions studied

1

Description of health condition studied

Renal stone

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

stone size

Timepoint

Before the intervention, during the intervention, 2 weeks after the intervention

Method of measurement

According to the paraclinical report: ultrasound, CT scan, IVP

2

Description

Stone-free rate

Timepoint

2 weeks and 2 months after extracorporeal shockwave lithotripsy (ESWL)

Method of measurement

According to the paraclinical report: ultrasound, CT scan, KUB

3

Description

stone place

Timepoint

Before the intervention, during the intervention, 2 weeks after the intervention

Method of measurement

According to the paraclinical report: ultrasound, CT scan, IVP

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: This study does not have a control group, and in that intervention, extracorporeal lithotripsy (ESWL) is performed on all patients (children).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Labafinejad Hospital

Full name of responsible person

Behrooz Shirzad

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Labafi nezhad hospital , 9th Boostan , pasdaraan ,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziai

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Arabi st. (Parvaneh), Student Blvd., Volejnak, 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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Behrooz Shirzad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available