Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 21 2360 2139

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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
Tehran
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 , Tehran

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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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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