

# 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., Volejnak, 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

**Street address**

Labafi nezhad hospital , 9th Boostan , pasdaraan ,  
Tehran

**City**

Tehran

**Province**

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**Postal code**

1478798771

**Phone**

+98 21 2360 2139

**Email**

behroozsh0457@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Ali Ziai

**Street address**

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

**Street address**

No. 7,5t Baharan Alley, South Iranshahr St, North  
Jannat Abad

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Behrooz Shirzad

**Position**

Resident

**Latest degree**

Bachelor

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## Person responsible for updating data

#### Contact

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Shahid Beheshti University of Medical Sciences

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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