

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of kidney possible damage after Extracorporeal Shock Wave Lithotripsy on children through surveying the level of urinary Neutrophil Gelatinase-associated Lypocalin Concentration

Protocol summary

Study aim

determine the potential damage to the kidneys following the Extracorporeal Shock Wave Lithotripsy on children by examining the level of urinary Neutrophil Gelatinase-associated Lypocalin Concentration

Design

Clinical trials include one group with no randomization and blindness. The trial phase does not apply to this study. This study is done to evaluate the potential damage to extracorporeal stones. The sample size is 120 people and these individuals are selected from among patients suffering from urinary stones referred to Nephrology Clinic of Imam Reza Hospital in Kermanshah.

Settings and conduct

The statistical population included all patients with urinary stones referring to Nephrology Clinic of Imam Reza Hospital in Kermanshah, 120 of them will be selected in accessible form. ESWL will be done at Imam Reza Hospital in Kermanshah. Before and 2-4 hours and 7 days after ESWL, the patients are evaluated for the number and size of the stone, as well as the level of urea, creatinine, and urinary Neutrophil Gelatinase-associated Lypocalin (NGAL) Concentration. The ESWL treatment process with shock energy range of 400 to 1000 Jules, a shock rate of 60, 90 and 120 times per minute, is applied by the storz medical crusher, made in Switzerland, to the troubled kidneys of these patients in a physically rested and steady state. At all stages of the evaluation, urine samples taken at a negative temperature of 80 degrees Celsius are maintained and the level of NGAL Concentration and other relevant variables is measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of urinary stones; Age 3 months to 17 years. Exclusion criteria: Certain and chronic diseases

Intervention groups

This study does not have a control group, in which intervention is done on all patients by performing Extracorporeal Shock Wave Lithotripsy(ESWL).

Main outcome variables

Urinary NGAL level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039715N1**

Registration date: **2018-07-13, 1397/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-13, 1397/04/22**

Update count: **0**

Registration date

2018-07-13, 1397/04/22

Registrant information

Name

Sara Hookari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of kidney possible damage after Extracorporeal Shock Wave Lithotripsy on children through surveying the level of urinary Neutrophil Gelatinase-associated Lypocalin Concentration

Public title

Evaluation of Extracorporeal Shock Wave Lithotripsy damage

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of urinary stones using any of the diagnostic methods (sonography, LVP, KUB) and with the approval of the designer Age 3 months to 17 years

Exclusion criteria:**Age**

From **3 months** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences Kermanshah

City

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Province

Kermanshah

Postal code

6719851115

Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

kums.rec.1397.03

Health conditions studied**1****Description of health condition studied**

Urinary stones

ICD-10 code

N18.1

ICD-10 code description

Chronic kidney disease, stage 1

Primary outcomes**1****Description**

Urinary associated Lypocalin Concentration level

Timepoint

Beginning of the study, 2-4 hours and 7 days after ESWL

Method of measurement

The level of urinary NGAL is measured using the kit (ELISA) and according to the manufacturer's instructions (Chines)

Secondary outcomes

empty

Intervention groups**1****Description**

This study does not have a control group, in which intervention is done on all patients by performing Extracorporeal Shock Wave Lithotripsy (ESWL). The ESWL treatment process with shock energy range of 400 to 1000 Jules, a shock rate of 60, 90 and 120 times per minute, is applied by the storz medical crusher, made in Switzerland, to the troubled kidneys of these patients in a physically rested and steady state.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center**

Name of recruitment center

Imam Reza Hospital-Pediatric Nephrology Clinic

Full name of responsible person

Dr. Ali Soroush

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Bagh abrisham Blvd, Imam Reza Hospital

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Kermanshah University of Medical Sciences

Full name of responsible person

Edris Khaledi

Position

Student

Latest degree

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Other areas of specialty/work

Pediatrics

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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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

Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

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Position

reasercher

Latest degree

Master

Other areas of specialty/work

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

I still have no plans for it

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

Yes - There is 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

Title and more details about the data/document

I still have no plans for it

When the data will become available and for how long

I still have no plans for it

To whom data/document is available

I still have no plans for it

Under which criteria data/document could be used

I still have no plans for it

From where data/document is obtainable

I still have no plans for it

What processes are involved for a request to access data/document

I still have no plans for it

Comments