Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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
Kermanshah
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

Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Kermanshah University of Medical Sciences

Full name of responsible person
Edris Khaledi

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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Biostatistics

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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