

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Survey of changes in serum markers of tissue damage after Extra corporeal shock wave lithotripsy in patients with kidney stones referred to lithotripsy center of Zabol in 1395

Protocol summary

Summary

Objectives: investigate the effect of extracorporeal shock wave lithotripsy (ESWL) on changes in serum factors of tissue damages in patients with kidney stones. Design: analytic epidemiological study. Setting and conduct: 120 patients with kidney stone referred to Lithotripsy Clinic's in Amirmomenin (AS) Hospital of Zabol, Iran, are selected by convenience sampling method. Inclusion criteria: having age between 12 to 70 years. exclusion criteria: chronic kidney disease and liver; pancreatitis; infections. Intervention: The overall aim of this is to In total, Inclusion criteria are having kidney stones and age between 12 to 70 years . Exclusion criteria include chronic kidney and liver diseases; pancreatitis and infections. Demographic information of the patients is recorded and then 5 cc of blood sample are collected before lithotripsy and 3 hours and 24 hours after ESWL and then are transferred into clot activator tube to the hospital laboratory. main outcome measures Variables: enzymes of alanine aminotransferase; aspartate aminotransferase; alkaline phosphatase; amylase; lipase; troponin I (cardiac enzyme); cpk-mb and PK-total; as well as bilirubin and albumin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082328927N2**
Registration date: **2016-11-15, 1395/08/25**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-15, 1395/08/25

Registrant information

Name

Fatemeh Khajehmahmoud

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3238 1400

Email address

khajeh.f@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zabol University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-09-18, 1395/06/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of changes in serum markers of tissue damage after Extra corporeal shock wave lithotripsy in patients with kidney stones referred to lithotripsy center of Zabol in 1395

Public title

changes in serum markers of tissue damage after Extra corporeal shock wave lithotripsy in patients with kidney stones

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: having age between 12 to 70 years.
exclusion criteria: chronic kidney disease and liver;
pancreatitis; infections.

Age

From **12 years** old to **69 years** old

Gender

Both

Phase

2-3

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 Zabol University of Medical Sciences

Street address

University of Medical Sciences, St. Martyr Bagheri,
Zabol.

City

Zabol

Postal code

009861663335

Approval date

2016-03-12, 1394/12/22

Ethics committee reference number

Zbmu.1.rec.1394.144

Health conditions studied

1

Description of health condition studied

kidney stone

ICD-10 code

N20.2

ICD-10 code description

Calculus of kidney with calculus of ureter

Primary outcomes

1

Description

Alanine aminotransferase

Timepoint

before ESWL; 3 and 24 hour after ESWL

Method of measurement

Blood samples

2

Description

Aspartate aminotransferase

Timepoint

before ESWL; 3 and 24 hour after ESWL

Method of measurement

Blood samples

3

Description

Alkaline phosphatase

Timepoint

before ESWL; 3 and 24 hour after ESWL

Method of measurement

Blood samples

4

Description

amylase

Timepoint

before ESWL; 3 and 24 hour after ESWL

Method of measurement

Blood samples

5

Description

Lipase

Timepoint

before ESWL; 3 and 24 hour after ESWL

Method of measurement

Blood samples

6

Description

Cardiac enzyme troponin I

Timepoint

before ESWL; 3 and 24 hour after ESWL

Method of measurement

Blood samples

7

Description

Cpk-mb enzymes

Timepoint

before ESWL; 3 and 24 hour after ESWL

Method of measurement

Blood samples

8

Description

The enzyme CPK-total

Timepoint

before ESWL; 3 and 24 hours after ESWL

Method of measurement

Blood samples

9

Description

Bilirubin

Timepoint

before ESWL; 3 and 24 hours after ESWL

Method of measurement

Blood samples

10

Description

albumin

Timepoint

before ESWL; 3 and 24 hours after ESWL

Method of measurement

Blood samples

Secondary outcomes

empty

Intervention groups

1

Description

Demographic information of the patients is recorded and then before lithotripsy and 3 hours and 24 hours after ESWL 5 cc of blood sample are collected and then are transferred into clot activator tube to the hospital laboratory.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

lithotripsy Clinic

Full name of responsible person

Khajehmahmood Fatemeh

Street address

lithotripsy Clinic, Amiralmomenin (AS) Hospital, 3km road of Zabol- Zahedan, Zabol.

City

Zabol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zabol University of Medical Sciences

Full name of responsible person

Sepehri Zahra

Street address

Vice president of research office, University of Medical Sciences, St. Martyr Bagheri.

City

Zabol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Zabol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zabol Medical Sciences

Full name of responsible person

Khajehmahmood Fatemeh

Position

Master of nursing

Other areas of specialty/work

Street address

Amiralmomenin (AS) Hospital, 3km road of Zabol- Zahedan, Zabol.

City

Zabol

Postal code

Phone

+98 54 3229 5125

Fax

Email

fatemekhaje34@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zabol university of medical sciences

Full name of responsible person

Afsharimoghaddam Amin

Position

Assistant Professor of Urology

Other areas of specialty/work**Street address**

Vice president of Educational office, Vice president of research office, University of Medical Sciences, St. Martyr Bagheri.

City

Zabol

Postal code**Phone**

+98 54 3229 5125

Fax**Email**

amn7afsharim@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Zabol university of medical sciences

Full name of responsible person

Khajehmahmood Fatemeh

Position

Master of nursing

Other areas of specialty/work**Street address**

Amiralmomenin (AS) Hospital, 3km road of Zabol-Zahedan, Zabol.

City

Zabol

Postal code**Phone**

00

Fax**Email**

fatemekhaje34@gmail.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty