

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial of study the effects of Extracorporeal shock wave lithotripsy in simple renal cyst formation in patients with renal stone with age under 35 years old

Protocol summary

Summary

The objective of this study is to identify the connection between Extracorporeal Shock wave Lithotripsy (ESWL) and formation of renal cyst in short term. The link between the amount of energy of the shock waves and the number of induced shocks to each kidney will also be studied in this research. This study will be conducted on patients who have been diagnosed with renal stone at Behboud Hospital's Lithotripsy Center. In this study, 30 patients, under the age of 35, who have been diagnosed with unilateral renal stone and have no history of renal cyst are chosen as the intervention group and the opposite kidney of the same group of patients is considered as the control group. The main inclusion criteria for this study are: Patients who have been diagnosed with unilateral Renal stone and need to do ESWL; without any history of renal cyst; age under 35 years old. Also, the main exclusion criteria are: any other medical treatment other than ESWL for Renal stone; History of renal cyst; age above 35 years old. Before ESWL, Sonography will be performed to ensure absence of renal cyst. During the next step, patients will receive ESWL treatment, and the number of induced shock waves and the amount of energy entered to each kidney during each treatment will be recorded. Both kidneys will be studied in 9 months by performing sonography to identify the possibility of cyst formation and the size of the renal stone.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607179904N2**

Registration date: **2016-09-22, 1395/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-22, 1395/07/01

Registrant information

Name

Mohsen Amjadi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 411584153

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amjadm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Researcher

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-07-21, 1394/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of study the effects of Extracorporeal shock wave lithotripsy in simple renal cyst formation in patients with renal stone with age under 35 years old

Public title

Study the effects of lithotripsy in renal cyst formation

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion Criteria: Patients who have been diagnosed with unilateral kidney stone and need to do Lithotripsy; without any history of renal cyst; age under 35 years old
Exclusion Criteria: Any other medical therapy other than Lithotripsy for kidney stone; History of kidney cyst; age above 35 years old

Age

To 35 years old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

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 Tabriz University of Medical Sciences

Street address

Central Building, Tabriz University of medical Science, Golgasht St.

City

Tabriz

Postal code

Approval date

2015-07-27, 1394/05/05

Ethics committee reference number

TBZMED.REC.1394.400

Health conditions studied

1

Description of health condition studied

Renal Stone

ICD-10 code

N20

ICD-10 code description

Calculus of kidney

2

Description of health condition studied

Renal Cyst

ICD-10 code

N28.1

ICD-10 code description

Cyst of kidney, acquired

Primary outcomes

1

Description

Simple Renal Cyst Formation

Timepoint

9 month after ESWL

Method of measurement

Sonography

2

Description

The amount of energy received by each kidney in each session

Timepoint

During ESWL

Method of measurement

Questionnaire

3

Description

The number of shock waves received by each kidney in each session

Timepoint

During ESWL

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Size of renal stone after ESWL

Timepoint

9 month after ESWL

Method of measurement

Sonography

Intervention groups

1

Description

Control Group : No action

Category

N/A

2

Description

Interventionl Group : Extracorporeal shock wave lithotripsy done for 20 minutes on target kidney.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Behboud Hospital`s Lithotripsy Center

Full name of responsible person

Ali Azari

Street address

Southern army Street, Cross Baghshmal

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Elham Azari

Street address

Faculty of Medicine, Tabriz University of Medical Science, Golgasht Street

City

Tabriz

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 of Tabriz 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

Tabriz University of Medical Science

Full name of responsible person

Hamidreza Mousavi Mirak

Position

Medicine student, Coworker

Other areas of specialty/work

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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