

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of cystone on stone expulsion after extracorporeal shock wave lithotripsy: a randomized clinical trial

Protocol summary

Summary

The aim of this study is evaluation of efficacy of cystone on stone expulsion after extracorporeal shock wave lithotripsy (ESWL). Study design: After explaining the purpose of the study and obtaining the informed consent, patients will be randomly allocated into intervention and control group. Randomization will be performed using random block sizes of 4. The study is randomized, placebo-free, single-center, phase 3 trial. Inclusion criteria : Patients with kidney stones < 2 cm. Exclusion criteria: history of kidney surgery; concurrent use of other drugs for treatment of kidney stones; hydronephrosis. sample size:100 patients are participated in the study with 50 patients in each group.The intervention used in the study: cystone 5 mg orally twice daily from the beginning of Lithotripsy (ESWL) until one month. Primary outcomes: accelerate expulsion of stone after Lithotripsy; Reducing the side effects of other drugs such as hydrochlorothiazide after Lithotripsy; Preventing the need for surgery after Lithotripsy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042221900N1**

Registration date: **2016-08-31, 1395/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-31, 1395/06/10

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Islamic Azad University of Shahrood

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cystone on stone expulsion after extracorporeal shock wave lithotripsy: a randomized clinical trial

Public title

The effect of cystone on stone expulsion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with kidney stones smaller than 2 cm. Exclusion criteria: history of kidney surgery, Concomitant use of other drugs for treatment of kidney stones; hydronephrosis.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be performed using random block sizes of 4.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrood University of Medical Sciences

Street address

Shahrood University of Medical Sciences, Haft Tir Square, Shahrood

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Shahrood

Postal code

3613773955

Approval date

2015-01-21, 1393/11/01

Ethics committee reference number

930/32

Health conditions studied

1

Description of health condition studied

Kidney and urinary tract stone

ICD-10 code

N20.N21.N2

ICD-10 code description

N20 Calculus of kidney and ureter - N21 Calculus of lower urinary tract - N22* Calculus of urinary tract in diseases classified elsewhere- N23 Unspecified renal colic

Primary outcomes

1

Description

Kidney stone expulsion

Timepoint

Before and one month after intervention

Method of measurement

Abdominal X-ray, CT scan and sonography

Secondary outcomes

1

Description

Therapy sessions of kidney Lithotripsy

Timepoint

Six months after the first Lithotripsy

Method of measurement

Record number of doing Lithotripsy

Intervention groups

1

Description

Intervention group: Cystone 5 mg oral tablet, twice a day (every 12 hours) from the beginning of Lithotripsy until one month.

Category

Treatment - Drugs

2

Description

Control group: Non-use of cystone 5 mg oral tablet

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein education, Research and Treatment Center, Shahrood

Full name of responsible person

Dr.Amin Amini.Urologist

Street address

City

Shahrood

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology, Islamic

Azad University of Shahrood
Full name of responsible person
Dr Sahebali Manafi
Street address
Islamic Azad University of Shahroud, Tehran Blvd
City
Shahrood
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 and Technology, Islamic Azad University of Shahrood
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

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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