Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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

Azadeh Khamedi

Name of organization / entity

Islamic Azad University Shahrood branch

Country

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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
City
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 begining 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

Name of organization / entity
Islamic Azad University of Shahroud

Full name of responsible person
Azade khamedi

Position
Medical Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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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