Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The evaluation of four plants extract effectiveness on renal stone passage in patients whom underwent extracorporeal shockwave lithotripsy, A double blind randomized clinical trial

Protocol summary

Study aim

To investigate the effect of consuming four plant extracts on kidney stone excretion following extracorporeal lithotripsy

Design

A concealed, randomized, blinded, sham controlled clinical trial, phase 3 design of 62 patients

Settings and conduct

We select 62 patients referred to the lithotripsy department of Imam Jafar Sadeq Hospital in Meybod with the aforementioned conditions whom undergo an abdominopelvic CT scan without contrast before lithotripsy. Then, the patient undergo lithotripsy, and randomized into two groups by concealed envelope. One group is given antibiotics and analgesics and syrup of four herbal extracts, the other receive placebo for 40 days (10 cc, three times a day). Then, a kidney ultrasound has been done. At the end of the study, the presence or absence of stones and the size of the stone remnants are checked and compared between two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The stone size is between 1-2 cm. 2. The stone's Hounsfield number is below 1000. 3. The age is over 18 years. 4. The distance between the stone and the skin surface is less than 10 cm. Exclusion criteria: 1. Urinary tract infection symptoms 2. History of DJ insertion; 3. Does not consent to participate in the study 4. Developing post-ESWL complications 5. Does not complete post-lithotomy follow-up. 6. Any anatomical abnormalities in the kidney undergoing lithotripsy. 8. Pregnant women and children. 9. Allergy to any of the ingredients of the prescribed drug

Intervention groups

The intervention group (31 eligible patients) is given antibiotics, painkillers, and extracts of four herbs for 40 days (three times a day, 10 cc each time). The control group (31 eligible patients) is given antibiotics, painkillers, and a placebo for 40 days (three times a day, 10 cc each time).

Main outcome variables

Stone passage rate after extracorporeal lithotripsy following drug use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241219064101N2**
Registration date: **2025-03-11, 1403/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-11, 1403/12/21**
Update count: **0**

Registration date

2025-03-11, 1403/12/21

Registrant information

Name

Amir hossein Rahavian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4478 7300

Email address

m.farhadpour2005@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-10, 1403/12/20

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of four plants extract effectiveness on renal stone passage in patients whom underwent extracorporeal shockwave lithotripsy, A double blind randomized clinical trial

Public title

The evaluation of four plants extract effectiveness on renal stone passage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with kidney stones and candidates for extracorporeal shockwave lithotripsy The Hounsfield unit of the stone< 1000 The age>18 years The distance between the stone and the skin surface< 10 cm The stone size is between 1-2 cm

Exclusion criteria:

Febrile patients or active UTI History of renal lithotripsy and DJ insertion Not consenting to participate in the study Any complications during or after ESWL Failure to comply their post-lithotripsy follow-up. Any anatomical abnormalities in the kidney undergoing lithotripsy History of CT Scan for any reason in the past year Pregnant women and children. Consumption of antiplatelet and anticoagulant drugs Consumption of other drugs due to any underlying disease. History of allergy to the ingredients of the four-herb extract drug

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

They are randomly divided into two groups using the envelope method, which is provided to the patients by the secretary of the stone crusher department of Meybod Hospital. In order to randomly allocate eligible patients into two groups, we consider patients numbered 1 to 62 in the order of their referral, and then, using the Random Allocation Version 2 software, a random sequence is generated and individuals are placed in two intervention or control groups (A, B). The method of generating random codes is simple random. In order to blind the random allocation, the random allocation list is provided to another person who is outside the study, and the type of intervention is asked from this person based on the list by text message or phone.

Blinding (investigator's opinion)

Double blinded

Blinding description

Those who have been kept blind include: 1) the participants who are the same patients with kidney stones who are candidates for extra-organ stone crushing in the Stone Crushing Center of Imam Jafar Sadegh Meybod Hospital were included in the study under the conditions of entry and with consent. 2) The evaluator is an experienced and single radiologist who subjects all participants to kidney ultrasound after 40 days.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Working Group/Committee of Shahid Dr. Rahmanmun Hospital, Shahid Sadoughi University

Street address

Enghelab Avenue

City

Yazd

Province

Yazd

Postal code

8918815484

Approval date

2023-10-14, 1402/07/22

Ethics committee reference number

IR.SSU.SRH.REC.1402.025

Health conditions studied

1

Description of health condition studied

A study of patients with kidney stones who are candidates for extracorporeal lithotripsy

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description
Percentage of people who completely passed kidney stones after ESWL

Timepoint
forty days after lithotripsy and drug consumption

Method of measurement
Before stone crushing, we subject all patients to a CT scan of the abdomen and pelvis without injection to obtain accurate information about the stone, and we request a urine culture test for all patients to detect a possible urinary tract infection. Then the patients are subjected to stone crushing by an experienced personnel in the field of extracorporeal stone crushing and by a single device.40 days after stone crushing, patients are subjected to kidney ultrasound by an experienced radiologist and the presence or absence of stones and the size of stone remains are checked.

2

Description
Stone location

Timepoint
Before lithotripsy and forty days after lithotripsy and drug consumption

Method of measurement
Before lithotripsy, we subject all patients to a CT scan of the abdomen and pelvis without injection to obtain accurate information about the stone, and we request a urine culture test for all patients to detect a possible urinary tract infection. Then the patients are subjected to stone crushing by an experienced personnel in the field of extracorporeal stone crushing and by a single device.40 days after stone crushing, patients are subjected to kidney ultrasound by an experienced radiologist and the presence or absence of stones and the size of stone remains are checked.

3

Description
Stone size

Timepoint
Before lithotripsy and forty days after lithotripsy and drug consumption

Method of measurement
We perform a non-injection CT scan of the abdomen and pelvis before lithotripsy to obtain accurate information about the stone, and we request a urine culture test for all patients to detect possible urinary tract infection. Then, patients undergo lithotripsy by an experienced staff in the field of extracorporeal lithotripsy using a single device. Patients undergo renal ultrasound 40 days after lithotripsy by an experienced radiologist and the unit, and the presence or absence of stones and the size of the stone remnants are examined.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: this group, which includes 31 eligible patients, will be given antibiotics, painkillers, and extracts of four plants (nettle, thistle, horsetail, celery), and patients are advised to take the prescribed medications according to the instructions of the Urmia Farteb Company for forty days (10 cc, three times a day).

Category
Treatment - Drugs

2

Description
Control group: This group, which includes 31 eligible patients, will be given a placebo, which is also prepared by Urmia Farteb Company, which is mint extract, and is given to 31 patients with exactly the same packaging, and patients are advised to take the prescribed medications according to the instructions of the Urmia Farteb Company for forty days (10 cc, three times a day).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Meybod, Imam Jafar Sadiq (AS) Hospital

Full name of responsible person
Amirhossein Rahavian

Street address
Salamat Street, Janbaz Square, Basij Boulevard

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Postal code
8961977138

Phone
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Email
Meybodhospital@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Nooshin Shahd Urmia Company

Full name of responsible person
Davood Ahmadian

Street address
6th Km of Mahabad Road

City
Urmia
Province
West Azarbaijan
Postal code
5731139951
Phone
+98 44 3242 4330
Email
nooshinshahd@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nooshin Shahd Urmia Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd Shahid Sadoughi University of Medical Sciences Campus
Full name of responsible person
Amirhossein Rahavian
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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

Not applicable

Title and more details about the data/document

A part of the data such as the information related to the main outcome or the like can be shared.

When the data will become available and for how long

Access to study documentation after results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions, and also people who are working in the industry can apply for them.

Under which criteria data/document could be used

For secondary studies

From where data/document is obtainable

Traditional Medicine Research Center, Yazd Shahid Sadoughi University of Medical Sciences

What processes are involved for a request to access data/document

The request sent will be reviewed by the members of the center. If the members agree, they will be notified.

Comments

There is no further information.