

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Pilot study on the effectiveness of selected natural products from traditional Iranian medicine sources (Bore armani and Raphanus niger Mill. combination/mixture) on the treatment of kidney stones

Protocol summary

Study aim

Evaluating the effect of selected natural product (Bore armani and Raphanus niger Mill. combination/mixture) in the treatment of kidney stones

Design

The pilot study was performed on 10 patients with kidney stones 10 mm and smaller in size, which was diagnosed by ultrasound.

Settings and conduct

Patients with kidney and ureteral stones with a size of less than 10 mm who refer to Shariat Panahi Clinic, after the doctor's opinion, enter this study. Patients drink the medicine half an hour before breakfast and half an hour before lunch and half an hour before dinner in the evening with a glass of warm water sweetened with a tablespoon of honey. In order to evaluate the effectiveness and safety of the drug, it will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age 20-60 years 2- Presence of kidney or ureteral stones smaller than 10 mm based on ultrasound report 3- Absence of emergency conditions in the patient 4- Non-pregnancy and lactation in women 5- Blood creatinine less than 1.4 mg / dl 6- No kidney tumors 7- No insulin-dependent diabetes 8- No herbal medicine for kidney stones Inclusion criteria: 1- Existence of uncontrollable pain 2- Emergency cases of kidney stones or the need for surgical interventions

Intervention groups

Evaluation of the effectiveness of natural medicine and evaluation of possible side effects of the drug during treatment on the size and number of kidney and ureteral stones in patients by ultrasound and blood tests and a questionnaire are evaluated.

Main outcome variables

Comparison of renal stone size by renal ultrasound and 24-hour urinary calcium, magnesium, citrate and oxalate levels, also liver enzymes (ALT,AST), creatinine, blood

urea nitrogen (BUN) in the two groups before and after drug administration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200112046087N3**

Registration date: **2020-08-12, 1399/05/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-12, 1399/05/22**

Update count: **0**

Registration date

2020-08-12, 1399/05/22

Registrant information

Name

Hanieh Babaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

haniehbabaei92@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Pilot study on the effectiveness of selected natural products from traditional Iranian medicine sources (Bore armani and Raphanus niger Mill. combination/mixture) on the treatment of kidney stones

Public title
A pilot study to evaluate the effectiveness of selected drugs from traditional medicine sources on the treatment of kidney stones

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Kidney or ureteral stones less than 10 mm in size, according to ultrasound reports Pregnancy and lactation in women No kidney tumors Lack of emergency conditions in the patient No insulin-dependent diabetes Not taking any herbal medicine for kidney stones 20-60 years
Exclusion criteria:
Severe urinary tract infection Emergency cases of kidney stones or the need for surgical intervention

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **10**

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 committee of Shahid Beheshti University of Medical Sciences
Street address

Shahid Beheshti University of Medical sciences,
Daneshju Blv.
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2019-05-05, 1398/02/15
Ethics committee reference number
IR.SBMU.RETECH.REC.1398.050

Health conditions studied

1

Description of health condition studied

kidney stone

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

The size of the stone

Timepoint

Before entering the study (before starting the drug) and 8 days after starting the drug

Method of measurement

Kidney ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with kidney stones with a size of 10 mm and smaller than those diagnosed by ultrasound and according to their blood and urine tests are included in the plan with the opinion of a doctor. Patients take 2 oral capsules of 500 mg 3 times a day. This capsule contains powder obtained from the aqueous extract of black horseradish and also the powder of Armenian sugar. In this project, toxicological tests, etc. have been performed on the Armenian sugar used in this combination and its safety has been evaluated. . The duration of the intervention is one week.

Category

Treatment - Drugs

Recruitment centers

Recruitment center**Name of recruitment center**

Shahid Beheshti Faculty of Traditional Medicine
(Shariat Panahi Health School)

Full name of responsible person

Reza Ilkhani

Street address

No. 8, Shams Alley, Vali-e Asr Ave, The Faculty of
Traditional Medicine of Shahid Beheshti University of
Medical Sciences

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ilkhanir@sbmu.ac.ir

Sponsors / Funding sources**Sponsor****Name of organization / entity**

Shahid Beheshti Faculty of Traditional Medicine

Full name of responsible person

Somayeh Esmaeili

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No. 8, Shams Alley, Vali-e Asr Ave, The Faculty of
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sesmaeili@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti Faculty of Traditional Medicine

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding****Person responsible for general inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza ilkhani

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Ilkhani

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Ilkhani

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Blood and urine analysis data and ultrasound results of
patients

**When the data will become available and for how
long**

1401

To whom data/document is available

Researchers working in academic and academic
institutions

Under which criteria data/document could be used

Data will be available after the article is published.

From where data/document is obtainable

In charge of Dr. Reza Ilkhani's plan. Email:
ilkhanir@sbmu.ac.ir

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

After the email to Dr. Ilkhani, the information will be
provided at her discretion and with the approval of the
research assistant of Shahid Beheshti Faculty of
Traditional Medicine.

Comments