Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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

1

Recruitment center

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

Full name of responsible person
Reza Ilkhani

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

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Sponsors / Funding sources

1

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 Traditional Medicine of Shahid Beheshti University of Medical Sciences

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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
Academic

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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Person responsible for scientific inquiries

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Associate professor

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Traditional Medicine

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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
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