Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluating the effect of selected natural product (Bore armani and Raphanus niger Mill. combination/mixture) compared to placebo in the treatment of kidney stones, a double-blind study

Protocol summary

Study aim

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

Design

A randomized, double-blind, placebo-controlled clinical trial study was performed on 70 patients with kidney stones 10 mm smaller than those 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 of two blind sides (the patient and the researcher are blind). 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

Patients with kidney stones 10 mm in size and smaller than those diagnosed by ultrasound are performed. Inclusion criteria: 1. Age: 20-60 years 2. Kidney or ureteral stones less than 10 mm in size, according to ultrasound reports 3. Absence of emergency conditions in the patient 4. Non-pregnancy and lactation in women 5-Creatinine blood less than 1.4 mg / dl 6. No kidney tumors 7. No insulin-dependent diabetes 8. Not taking any herbal medicine to excrete kidney stones Exclusion criteria: 1- Uncontrollable pain 2. Emergency cases of kidney stone or need for surgical intervention

Intervention groups

We will compare the effect of natural medicine and placebo during treatment on the patients with a size less than 10 kidney stone

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: **IRCT20200112046087N2**
Registration date: **2020-05-18, 1399/02/29**
Registration timing: **prospective**

Last update: **2020-05-18, 1399/02/29**
Update count: **0**

Registration date

2020-05-18, 1399/02/29

Registrant information

Name

Hanieh Babaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

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haniehbabaei92@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of selected natural product (Bore armani and Raphanus niger Mill. combination/mixture) compared to placebo in the treatment of kidney stones, a double-blind study

Public title

Evaluation of the efficacy of natural product with placebo on renal stone therapy

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 Blood creatinine less than 1.4 mg/dl 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

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **1**

Patients with kidney stones smaller than 10 mm

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization. Block randomization is used with 4 blocks, which will be used to generate random sequences using Random Allocation software. Due to randomly generated sequences, patients enter the control and intervention groups. As these patients will be referred by the treating physician to the planter, a list of the names of the nominees will be provided with a row number, and a coin will be used to decide whether or not to assign the numbers to the intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this plan, the drug and placebo are prepared by the pharmacist. After preparing the drug, the pharmacist will insert a specific code of the medicine on the bottle. These codes are only available to the pharmacist, and no one knows what kind of medicine (medicine or placebo) until the end of the study. The shape and size of all drugs are the same and indistinguishable. Therefore, the project implementer uses the drugs randomly for each patient. At the end of the study, after collecting the data, with the help of a pharmacist, the codes related to the drug and the drug facade are distinguished from each other, but information about the drug and placebo is hidden for the analyzer. Only at the end of the study, The codes are decrypted and the necessary information is provided to the executor.

Placebo

Used

Assignment

Parallel

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

2020-02-09, 1398/11/20

Ethics committee reference number

IR.SBMU.REC.1398.160

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

Patients with kidney stones 10 mm in size and smaller than those diagnosed by ultrasound are screened by a physician based on their blood and urine tests. Patients take 2 oral capsules 3 times a day. This capsule contains the500 mg powder of blue horseradish extract and the Armenian borax powder in equal proportions. The drug was previously developed under a separate approved plan. In that plan, toxicological tests, etc., have been performed on the Armenian boulder used in this compound, and its safety has been evaluated. The intervention lasts one week.

Category

Treatment - Drugs

2

Description

Patients with kidney stones 10 mm in size and smaller than those diagnosed by ultrasound are screened by a physician based on their blood and urine tests. Patients take 2 placebo capsules 3 times, before each meal for one week. The prescribed capsule in the control group contains 500 mg of powdered dry Sangag bread. Which is packaged in exactly the same way as the intervention capsules

Category

Placebo

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

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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Email

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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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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

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Person responsible for updating data

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

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

Title and more details about the data/document
Information on changes in urinary, blood, and sonographic parameters 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
Request a printed article and oral explanations and guidance by email and academic identity

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
Email information to Dr. Ilkhani will be provided if he so desires and with the research assistant of Shahid Beheshti Traditional School of Medicine approve

Comments