

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation the effect of Iranian Traditional Medicine (Persian Medicine) dietary recommendations on metabolic risk factors in calcium or radio-opaque kidney stones: a controlled randomized clinical trial

Protocol summary

Study aim

Determining the effect of traditional Iranian Medicine (persian medicine) diet recommendations in comparison with Evidence Based diet Recommended by the Stone Prevention Clinic on metabolic risk factors in patients with calcium or radioopaque kidney stones

Design

The randomized controlled clinical trial with parallel group single blind design of 80 patients with calcium or radio opaque kidney stones

Settings and conduct

This study is a randomized controlled clinical trial that patients with calcium or radioopacitis, who referred to a stone prevention clinic of Shahid Labbafinejad Hospital who are eligible to attend the study are enrolled. Then, the patients were randomly divided into two groups of control (recipient-based evidence based recommended by the Stone Prevention Clinic) and the intervention group (the recipient of the Iranian traditional medicine regime).

Participants/Inclusion and exclusion criteria

Non-pregnant and non-lactating women Men People with calcium stone or Patients with Radioopacitis stone in radiology At least once the recurrence of the stone. Are not under the special regime to prevent kidney stones, At least 20 days have passed since their last treatment interventions. 18 to 65 years old

Intervention groups

treatment group: Receiving Dietary Recommendations of Iranian Traditional Medicine to reduce recurrence of kidney stone and improve 24-hour urinary metabolic factors. control group: Providing evidence-based diet based on international guidelines

Main outcome variables

Comparison of the PH value of morning urine, 24-hour urine calcium, magnesium, creatinine, sodium, potassium, chlorine, and citrate in patients with calcium

kidney stones or radioopacitis in two groups Comparison of supersaturation index of calcium oxalate, calcium phosphate and uric acid 24-hour urine in two groups

General information

Reason for update

The investigation is over

Acronym

IRCT registration information

IRCT registration number: **IRCT20190928044906N1**

Registration date: **2019-11-11, 1398/08/20**

Registration timing: **prospective**

Last update: **2021-07-06, 1400/04/15**

Update count: **3**

Registration date

2019-11-11, 1398/08/20

Registrant information

Name

Fatemeh Kargarsharifabad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

f.kargarsharif@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-21, 1398/08/30

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date

2019-11-21, 1398/08/30
Actual recruitment end date
2021-04-20, 1400/01/31
Trial completion date
2021-06-21, 1400/03/31

Scientific title

Evaluation the effect of Iranian Traditional Medicine (Persian Medicine) dietary recommendations on metabolic risk factors in calcium or radio-opaque kidney stones: a controlled randomized clinical trial

Public title

Effect of persian medicine dietary recommendations in kidney stone

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Non-pregnant and non-lactating women Men Patients referred to the Stone Prevention Clinic of Labbafinejad Hospital which can perform tests and follow-up to implement the plan People with calcium stone or Patients with Radioopacitis stone in radiology At least once the recurrence of the stone. Are not under the special regime to prevent kidney stones, At least 20 days have passed since their last treatment interventions. 18 to 65 years old

Exclusion criteria:

GFR less than 60 24-hour urinary oxalate above 40 mg Which changed to over 60mg Taking drugs affecting calcium metabolism such as calcium supplements Taking oxalate or supresturation modifier drugs like vitamin B6, magnesium, potassium citrate, allopurinol liver failure diseases, diabetes, hyperthyroid, hyperparathyroid disease, immunopathogenic diseases, cancer, chronic diarrhea, chronic kidney failure and urinary tract infection Taking anti-obesity drugs to absorb fat-soluble inhibitors such as: Orlistate Taking herbal medicines less than a month before studying or during the study Pregnant and lactating women Added condition: Do not change the dose of blood pressure medication one month before the plan and during the plan

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **43**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization. Block randomization with block size of four will be used. Random Allocation software will be used to generate the stochastic sequence. According to the randomly generated sequences, patients enter the control group and the intervention group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2018-02-19, 1396/11/30

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.1405

Health conditions studied

1

Description of health condition studied

Diet in nephrolithiasis

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

24-hour urinary calcium oxalate supersaturation

Timepoint

The beginning of the study and the end of the two-month diet

Method of measurement

Litorsk Software

2

Description

24-hour urinary uric acid supersaturation

Timepoint

The beginning of the study and the end of the two-month diet

Method of measurement

Litorsk Software

3

Description

24-hour urinary calcium phosphate supersaturation

Timepoint

The beginning of the study and the end of the two-month diet

Method of measurement

Litorsk Software

Secondary outcomes

1

Description

Evaluate foods eaten (Food recall)

Timepoint

The beginning and the end of the study

Method of measurement

Nutrition 4 software

Intervention groups

1

Description

Intervention group: Diet based on traditional Iranian medicine books and scientists such as Ibn Sina to control recurrence of stone and improve urinary supersaturation of calcium oxalate and calcium phosphate and uric acid. This diet includes orders to Reforming eating etiquette and improve digestion and orders for non-consumption of harmful foods from the viewpoint of Iranian traditional medicine in kidney stone patients Such as contraindicated yogurt, cheese, and pasta and... etc.

Category

Treatment - Other

2

Description

Control group: The diet used in Shahid Labbafinejad Medical Center is based on European and American guidelines to control recurrence of stone and improve urinary supersaturation of calcium oxalate and calcium phosphate and uric acid. This regime includes orders such as increasing fluid consumption and eating adequate dairy and reducing salt consumption and ...etc.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Prevention Clinic of Shahid Labafi Nejad Hospital

Full name of responsible person

Reza Ilkhani

Street address

No. 8, Shams Alley, Valie Asr

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Shahid Beheshti School of Traditional medicine

Full name of responsible person

Reza Ilkhani

Street address

Shahid Beheshti School of Traditional medicine, No. 8, Shams Alley, Valie Asr Ave, Tehran

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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

Research deputy of Shahid Beheshti School 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

Fatemeh Kargarsharif

Position

phd student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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

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Full name of responsible person

Reza Ilkhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

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 of the changes in urinary factors of patients will be available without ability to identify patients

When the data will become available and for how long

Starting from 2022

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Request the article and oral explanations and guidance by email and academic identity

From where data/document is obtainable

Responsible for the research project Dr Reza Ilkhani.

ilkhani@sbmu.ac.ir

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

After emailing Dr. Ilkhani on his discretion and confirmation of research assistant of Shahid Beheshti Faculty of Traditional Medicine, the information will be available in less than three weeks.

Comments