

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of boron supplementation on nutritional status, kidney stone size, improvement of clinical symptoms and some of the serum and urine biomarkers in patients with nephrolithiasis: a randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim

Determining the effect of boron supplementation on nutritional status, size of kidney stones, improvement of clinical symptoms and some biochemical indicators of serum and urine in patients with kidney stones

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 60 patients, RAS software was used for randomization.

Settings and conduct

This study will be performed on 60 patients in the clinics of Maragheh city and the packaging and coding of placebo capsules and the main supplement was done by a person outside the project and the prescriber of the supplement and the doctor reviewing the results of the project and other researchers. It does not matter which is a placebo or a supplement

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with kidney stones in the age range of 20-65 years and willing to cooperate Non-entry conditions: under 20 and over 65 years, pregnancy, lactation, cardiovascular disease, liver disease, gallstone, kidney failure, cancer, benign prostatic hyperplasia (BPH), hypothyroidism or hyperthyroidism, urinary tract infection, Estrogen therapy and regular consumption of vitamin supplements and herbal teas and alcohol consumption

Intervention groups

Intervention group 1: includes 20 people with kidney stones with inclusion criteria who will receive 10 mg of boron citrate supplement daily. Intervention group 2: including 20 people with kidney stones with inclusion criteria who will receive 10 mg of sodium tetrahydroborate daily. Control group: including 20 people with kidney stones with inclusion criteria who will receive 10 mg placebo daily containing corn starch.

Main outcome variables

Anthropometric Indices: body composition: Kidney stone size: clinical signs: ionized calcium, uric acid, urea, creatinine and alkaline phosphatase, urinary citrate and oxalate calcium and general urinalysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210914052469N1**

Registration date: **2021-12-06, 1400/09/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-06, 1400/09/15**

Update count: **0**

Registration date

2021-12-06, 1400/09/15

Registrant information

Name

gita vousoughi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3746 1910

Email address

gitvous@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of boron supplementation on nutritional status, kidney stone size, improvement of clinical symptoms and some of the serum and urine biomarkers in patients with nephrolithiasis: a randomized, double-blind, placebo-controlled trial

Public title

"Evaluation of the effect of boron on kidney stones"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with kidney stones in the age range of 20-65 years and willing to cooperate

Exclusion criteria:

Age under 20 and over 65 years Pregnancy
Breastfeeding Cardiovascular disease Bile stone Kidney failure Cancer Benign prostatic hyperplasia (BPH)
Hypothyroidism or hyperthyroidism Urinary tract infection Estrogen therapy Regular use of vitamin supplements and herbal teas and Alcohol consumption

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is simple and available and the randomization tool will be random allocation software that in addition to simple randomization, this software will be able to random allocation by block method (randomization Block) and randomly sequence the supplement or placebo. First, patients are blocked according to sex and then using block randomization method and blocks of four will be divided into two groups of intervention and placebo. To hide random allocation or not specify the type of intervention before assigning a person to a specific group, opaque sealed envelopes with random sequences will be used, in which each of the random sequences created on a card will be used. It is registered and the cards are placed in the letter envelopes in order.

In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. At the beginning of the registration of participants, according to the order of entry of participants, according to the order of entry of eligible participants to study, one of the envelopes is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

60 eligible patients will be randomly assigned to one of the intervention or control groups based on the blocks created by the random allocation software. The generated random sequence is kept in a safe place and performed by an independent third party who is blind to the trial during the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

third house from the left, Oval dead end from the right, Ghaem Alley, Etihad Alley, 20 meters from Etihad Alley, Pasdaran St

City

Maraghe

Province

East Azarbaijan

Postal code

5516946418

Approval date

2021-10-25, 1400/08/03

Ethics committee reference number

IR.TBZMED.REC.1400.673

Health conditions studied**1****Description of health condition studied**

kidney stone

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

Kidney stone size

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Ultrasound

2

Description

Improve clinical symptoms

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Questionnaire

3

Description

Anthropometric indicators include: weight, height, waist circumference, hip circumference

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Weight is measured using a Seca calibrated scale with an accuracy of 0.1 kg and with a minimum of clothing in the early morning in the form of fasting and measuring height, waist circumference and hip circumference using a tape measure with an accuracy of 0.1 cm.

4

Description

Serum levels of ionized calcium, phosphorus, uric acid, urea, creatinine and alkaline phosphatase

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

At the beginning and end of the study, fasting blood samples will be taken from all participants after 8-12 hours of fasting in the central laboratory of Maragheh. Determination of serum level of the studied variables is done according to the relevant protocol. Also, part of the serum sample is stored in a freezer at -70 degrees.

5

Description

Urine analysis (measurement of citrate and oxalate and urinary calcium and general urinalysis)

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

At the beginning and end of the study, random urine samples will be taken from all participants in Maragheh Central Laboratory and urine analysis will be performed.

6

Description

Body composition measurements include fat mass, lean body mass, total body water

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Using the BIA (Bioelectric Impedance Analyser) device, fasting (10-12 hours fasting) has done

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Boron citrate, dose: 5 mg per capsule, number of times: twice a day, time of use: 2 months, Manufacturer: Nutrition Research Center and School of Pharmacy, Tabriz University of Medical Sciences.

Category

Treatment - Drugs

2

Description

Intervention group 2: Sodium tetrahydroborate, dose: 5 mg per capsule, number of times: twice a day, time of use: 2 months, Nutrition Research Center and School of Pharmacy, Tabriz University of Medical Sciences.

Category

Treatment - Drugs

3

Description

Control group: corn starch, dosage: 5 mg per capsule, number of times: twice a day, time of use: 2 months, Nutrition Research Center and School of Pharmacy, Tabriz University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khajeh Nasir Clinic and Other Medical Centers in Maraghe

Full name of responsible person

Gita Vousoughi

Street address

No.64, Farvardin Alley., North Khajeh Nasir Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tabriz University of Medical Sciences
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
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Full name of responsible person
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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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Title and more details about the data/document

The data will be confidential but the results of the study will be published based on the article

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of data is permitted for use in scientific research

From where data/document is obtainable

To receive data by email, refer to
ostadrahimi@tbzmed.ac.ir

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

Requests should be emailed to
ostadrahimi@tbzmed.ac.ir and information will be provided to the applicant within two weeks.

Comments