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
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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 Egular 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) hs 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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Full name of responsible person
Dr Alireza Ostad Rahimi
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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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Gita Vousoughi
Position
Master student of Clinical Nutrition
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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