

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effects of sodium pentaborate (NaB) supplementation on calculi status and related metabolic risk factors in patient with kidney stone

Protocol summary

Study aim

To determine effects of sodium pentaborate (NaB) supplementation on calculi status and related metabolic risk factors in patient with kidney stone.

Design

In this double blind randomized controlled trial with two parallel groups, 120 individuals will be selected by simple randomization. Then by using the Random Allocation Software, the subjects will be allocated into either pentaborate or placebo group, stratified BMI.

Settings and conduct

After registration of clinical trial, the researcher will identify the eligible individuals. All eligible persons who are willing to participate at the study will sign a written consent form, and afterward questionnaires will be complete. Ten ml of fasting blood sample will be taken for laboratory. Supplements and their placebo will be prepared in identical appearance. Participants and researchers will be blind.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Men and women aged 20-50 years; Patients with kidney stones with urologist diagnosis; Patients with kidney stones who, can be follow with drug therapy for a maximum of 3 month according to a urologist diagnosis; Not suffering from liver and kidney failure. Non-inclusion Criteria: Pregnancy or lactation; Suffering from other kidney related metabolic disorders and disease at the same time; Patients with obstructive, infectious, and ureter stones; and Emergency cases requiring special treatment or surgery with the diagnosis of urologists.

Intervention groups

The groups will receive sodium pentaborate or placebo (carboxymethyl cellulose) capsules 5 mg twice daily (every 12 hours) for 8 weeks.

Main outcome variables

Calculi status, Status of cardio-vascular disease and metabolic syndrome risk factors (Blood pressure, Anthropometric measures, Lipid profile, Fasting Blood

glucose), kidney functional tests (Urea, Creatinin, BUN, Uric acid, Analysis of urinary ions (Ca, k, Na), Serum PTH)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090609002017N34**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **prospective**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

Registration date

2019-04-07, 1398/01/18

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

ostadrahimi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-21, 1398/03/31

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of sodium pentaborate (NaB) supplementation on calculi status and related metabolic risk factors in patient with kidney stone

Public title
The effects of sodium pentaborate (NaB) supplementation on calculi status and related metabolic risk factors in patient with kidney stone

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Men and women aged 20-50 years Patients with kidney stones with urologist diagnosis (other than obstructive, infectious, and ureter stones) Patients with kidney stones who, can be follow with drug therapy for a maximum of 3 month, according to a urologist diagnosis Not suffering from liver and kidney failure Patients who are willing to participate in the study
Exclusion criteria:
Pregnancy or lactation Suffering from other kidney related metabolic disorders and disease, at the same time Smoking Having a special diet Patients with obstructive stones, infections, and ureter stones and Emergency cases requiring special treatment or surgery with the diagnosis of urologists Changes in the drug protocol during the study

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
From among the patients who volunteer to participate in the study, 120 individuals will be selected by simple randomization. Then by using the Random Allocation Software, the subjects will be allocated into either pentaborate or placebo group, stratified BMI.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the main investigators as well as the patients will be blinded to the type of the supplement (pentaborate or placebo) received by each group. The person responsible for preparing the supplement capsules (who is completely unrelated to the study) will be asked to assign a three digit code to each of the two capsules (sodium pentaborate and placebo), and keep

the codes for himself until the end of the study and data analyses.

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

Tabriz University of Medical Sciences, Attar Neyshabouri Av., Golgasht St.

City

tabriz

Province

East Azarbaijan

Postal code

5166/1573113

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.TBZMED.REC.1397.1023

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

Calculi status

Timepoint

Weeks 0, 4 and 8 study

Method of measurement

Ultra sonography

2

Description

Values of kidney functional tests (Urea, Creatinin, BUN, Uric acid, Analysis of urinary ions (Ca, k, Na), Serum PTH)

Timepoint

Before and after treatment

Method of measurement

Enzymatic methods, Atomic absorption, ELISA kit

3

Description

Status of metabolic syndrome

Timepoint

Before and after treatment

Method of measurement

Measurement of blood pressure with stethoscope, Measurement of waist circumference , Measurement of HDL-cholesterol, triglyceride, FBS and fasting Insulin through enzymatic methods

Secondary outcomes

1

Description

Values of liver functional tests (ALT_AST_ALP)

Timepoint

Before and after treatment

Method of measurement

Enzymatic methods

2

Description

Urine culture status

Timepoint

Before and after treatment

Method of measurement

Standard methods

3

Description

Dietary status (Dietary intake and Appetite)

Timepoint

Before and after treatment

Method of measurement

FFQ and VAS questionnaires

4

Description

Serum levels of oxidative Stress indices (Malondialdehyde (MDA) and Total antioxidant capacity)

Timepoint

Before and after treatment

Method of measurement

Spectrophotometry

5

Description

Status of some blood indices [PT(prothrombin time), ESR (erythrocyte sedimentation rate), INR (International Normalized Ratio), Albumin]

Timepoint

Before and after treatment

Method of measurement

Standard method, Westergren, Calculate, ELISA kit

Intervention groups

1

Description

intervention group: n= 80. Patients in this group will receive 2 capsules of sodium pentaborate (NaB) supplements for 8 weeks daily . each capsules contain 5 mg sodium pentaborate (NaB)

Category

Treatment - Drugs

2

Description

Control group: n= 30. Patients in this group will receive 2 capsules of placebo (Carboxymethyl cellulose) for 8 weeks daily . each capsules contain 5 mg Carboxymethyl cellulose. and 10 patients as a negative control will not receive any capsules.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition Research Center, Tabriz University of Medical Sciences,

Full name of responsible person

Dr. Alireza Ostadrahimi

Street address

Attar Neyshaburi Ave, Golgasht St, Nutrition Faculty.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 2292

Email

nut-rc@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Jouyban

Street address

No. 2 Central building of the university, Golgasht street, Azadi street

City

Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3335 7310
Fax
+98 41 3334 4280
Email
research-vice@tbzmed.ac.ir
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
Tabriz University of Medical Sciences
Full name of responsible person
Maryam Behrooz
Position
Ph.D. Candidate in Nutritional Sciences
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Faculty of Nutrition and Food Sciences, Attar Neyshabouri Av., Golgasht St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3335 2292
Email
mm.behroozp@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences
Full name of responsible person
Dr. Alireza Ostadrahimi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Nutrition Faculty, Attar Neyshaburi Ave, Golgasht St, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3335 2292
Email
ostadrahimi@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Maryam Behrooz
Position
Ph.D. Candidate in Nutritional Sciences
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Nutrition Faculty, Attar Neyshaburi Ave, Golgasht St, Tabriz, Ira
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3335 7582
Email
mm.behroozp@gmail.com

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

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

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

Title and more details about the data/document

Data collected for the primary outcomes will be shared.

When the data will become available and for how long

access starting 12 months after publication

To whom data/document is available

The data will only be available for people working in academic institution.

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers, for conducting Meta-analysis

From where data/document is obtainable

To access the required data, the researchers can contact Dr.alireza ostadrahimi. E-mail address: ostadrahimi@tbzmed.ac.ir

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

The applicant should provide a brief description of the aims and methods of his Meta-analysis. His request will be assessed by the researchers, and if all of them agree to the request, the requested data will be emailed to the applicant in an Excel file format. All these procedures will take no longer than 20 days.

Comments