Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

The effect of sodium pentaborate (NaB) supplementation on bone density, serum levels of bone turnover markers and inflammation-related microRNAs in postmenopausal women with primary osteoporosis: a triple blind randomized controlled trial.

Protocol summary

Study aim
To determine effect of sodium pentaborate supplementation on bone density, serum levels of bone turnover markers and inflammation-related microRNAs in postmenopausal women with primary osteoporosis

Design
In this triple blind randomized controlled trial with two parallel groups, ninety eligible women will be randomly assigned into the group receiving sodium pentaborate pentahydrate capsule and placebo using random permuted blocks and allocation ratio of 1 : 1.

Settings and conduct
After registration of clinical trial, the researcher will refer to the bone densitometry center at the Sina Educational Hospital and will identify the eligible women. All eligible women who are willing to participate at the study, will be invited to attend at the physical Medicine and Rehabilitation Research Center in a fasting state. After signing a written consent form, questionnaires will be complete. Ten ml of fasting blood sample will be taken for laboratory and genetic tests. Supplements and their placebo will be prepared in identical appearance. Participants, researchers, and statistical analyzer will be blind.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Postmenopausal women aged 50 to 65 years; Menstrual cessation for at least 12 consecutive months; Bone density between -1 to -2.5 in the lumbar, hip, or femoral neck. Non-inclusion Criteria: Renal diseases and failure; Bone disease other than osteopenia; The use of medications that affect bone metabolism.

Intervention groups
The groups will receive sodium pentaborate pentahydrate or placebo (carboxymethyl cellulose) capsules 5 mg twice daily (every 12 hours) for 6 months.

Main outcome variables
Mean bone density (BMD, T-score, and Z-score); Serum levels of bone turnover markers (Osteocalcin, P1NP, BSAP, CTX); Serum levels of inflammation-related microRNAs (miR422a، miR-133a، miR-21, miR-503)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20131009014957N7**
Registration date: **2019-03-30, 1398/01/10**
Registration timing: **prospective**

Last update: **2019-03-30, 1398/01/10**
Update count: **0**

Registration date
2019-03-30, 1398/01/10

Registrant information
Name
Azizeh Farshbaf-khalili
Name of organization / entity
Tabriz university of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date
2020-03-18, 1398/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of sodium pentaborate (NaB) supplementation on bone density, serum levels of bone turnover markers and inflammation-related microRNAs in postmenopausal women with primary osteoporosis: a triple blind randomized controlled trial.

Public title
The effect of sodium pentaborate (NaB) supplementation on bone density and serum levels of its related markers in postmenopausal women with primary osteoporosis.

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Postmenopausal women aged 50 to 65 years Menstrual cessation for at least 12 consecutive months Bone density between -1 to -2.5 in the lumbar or femoral neck

Exclusion criteria:
Renal diseases and renal failure Bone disease other than osteopenia The use of medications that affect bone metabolism

Age
From **50 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Ninety postmenopausal women with primary osteopenia will be randomly assigned into one of the two groups of receiving sodium pentaborate pentahydrate capsule and the group receiving placebo using random permuted blocks with sizes 4 and 6 and allocation ratio of 1 : 1 through RAS (Random Allocation Software).

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, researchers, participants and data analyzer will be blind regarding allocation into the groups. So that, supplements and their placebo will be prepared by the pharmaceutical company in a completely identical manner in terms of shape, color, dose, and odor. For each participant, 3 small opaque packs each containing 120 capsules for two month-use will be provided and placed in a large sealed and opaque pack. Large packs will be be numbered from 1 to 100 and will be opened from No. 1 to 100 in the order of participation of women in 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
Research Department., third floor., central construction number 2., Tabriz University of Medical Sciences., Golgasht Street., Azadi Avenue

City
Tabriz

Province
East Azarbaijan

Postal code
5143814998

Approval date
2019-02-25, 1397/12/06

Ethics committee reference number
IR.TBZMED.REC.1397.945

Health conditions studied

1

Description of health condition studied
Osteopenia

ICD-10 code
M85

ICD-10 code description
Other disorders of bone density and structure

Primary outcomes

1

Description
Bone mineral density

Timepoint
At the baseline (before intervention) and just after completion of the intervention (6 months after beginning

the intervention)

Method of measurement

Dual-energy X-ray absorptiometry (DXA)

2

Description

Serum levels of bone turnover markers (osteocalcin، P1NP، BSAP، CTX)

Timepoint

At the baseline (before intervention) and just after completion of the intervention (6 months after beginning of intervention)

Method of measurement

Using the ELISA method

3

Description

Serum levels of osteoporosis MicroRNA (miR422a، miR-133a، miR-21 و miR-503)

Timepoint

At the baseline (before intervention) and completion of the intervention (6 months after beginning intervention)

Method of measurement

Using the Real-Time PCR method

Secondary outcomes

1

Description

serum levels of biochemical factors (steroid (estrogen and testosterone) and thyroid (T3 and T4) hormones, lipid profiles, insulin resistance, FBS, total calcium, 25 (OH) D, BUN and creatinine)

Timepoint

At the baseline (before intervention) and completion of the intervention (6 months after beginning intervention)

Method of measurement

Using Spectrophotometer, ELISA method

2

Description

Serum levels of some inflammatory (TNF-α, HS-CRP, IL-6)and oxidative stress indices (TAC, SOD, MDA)

Timepoint

At the baseline (before intervention) and completion of the intervention (6 months after beginning intervention)

Method of measurement

Using Spectrophotometer, Calorie meter, and ELISA method

3

Description

response to treatment based on the frequency of gene polymorphisms (OPG gene rs2062377 polymorphism, RANKL gene rs9533090 polymorphism, LRP5 gene rs3736228 polymorphism, ESR1 gene rs4869742 polymorphism, ZBTB40 gene rs6426749 polymorphism)

Timepoint

Completion of the intervention (6 months after beginning intervention)

Method of measurement

Using PCR-RFLP method

4

Description

nutritional status (mean weight, BMI, waist circumference, waist to hip ratio, appetite score)

Timepoint

At the baseline (before intervention) and completion of the intervention (6 months after beginning intervention)

Method of measurement

Using the Seca digital scale, the Seca wall mounted stadiometer and the VAS questionnaire

5

Description

Body composition analysis score (PBF, MBF, SLM, LBM, VFM, TBW, Mineral)

Timepoint

At the baseline (before intervention) and completion of the intervention (6 months after beginning intervention)

Method of measurement

Using Body Composition Analyzer

6

Description

Adverse events

Timepoint

During Intervention

Method of measurement

Using a checklist

Intervention groups

1

Description

Intervention group: The Sodium Pentaborate group will receive 5 mg capsules twice daily (every 12 hours) for 6 months

Category

Prevention

2

Description

Control group: Placebo group will receive 5 mg capsules twice daily (every 12 hours) containing carboxymethyl cellulose for 6 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Physical Medicine and Rehabilitation Research Center
Full name of responsible person
Azizeh Farshbaf-Khalili
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Golgasht Street, Attar Neishaboori Ave, Imam Reza Hospital, Ground Floor, Research Center of Physical Medicine and Rehabilitation
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Azizeh Farshbaf-Khalili
Position
Assistant Professor
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
Requested data will be provided to researchers for statistical analysis of the submitted proposal (meta-analysis).
When the data will become available and for how long
Starting immediately after publication
To whom data/document is available
Data will be available to researchers as well as to journals.
Under which criteria data/document could be used
The data will be available to researchers upon request and submission of a proposal to perform meta-analysis using IPD data after being unidentified. Also, in exceptional cases, data will be made available to journals for checking.
From where data/document is obtainable
Refer to the email address (farshbafa@tbzmed.ac.ir).
What processes are involved for a request to access data/document
The requests will be sent by email and data will be available within a week.
Comments