

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Sep 2026

The effect of boron citrate supplementation on nutritional status, cardiometabolic factors, and inflammatory indices of TNF- α , IL-10, IL-6, and CRP and serum level of thyroid hormones and oxidative stress indices of SOD, PAB, GPx, TAC and gene expression of TNF- α , IL-10, IL-6, CRP, PPAR- γ , SIRT1, PGC-1 α , AMPK in obese people

Protocol summary

Study aim

The effect of boron citrate supplementation on nutritional status, cardiometabolic factors, inflammatory indices, serum level of thyroid hormones and oxidative stress indices in obese people

Design

randomized, double-blinded, controlled trial, containing supplement and intervention groups, with parallel groups, sample size of 60 participants (30 in each group), RAS (Random Allocation Software) used for randomization.

Settings and conduct

This study will be conducted on 60 obese patients at Tabriz University of Medical Sciences Faculty of Nutrition. Patients will be divided into 2 equal groups of supplement and placebo and will receive boron citrate and placebo (maltodextrin) respectively for 12 weeks. In order to blind all researchers and participants, a person not involved in the experiment randomly assigns a list to the participants in each group and labels all identical containers (in appearance and color) according to their number. Therefore, participants will be unaware of the type of intervention they are receiving. The random sequence will also be unpredictable.

Participants/Inclusion and exclusion criteria

Inclusion criteria: obese people/Exclusion criteria: pregnancy and breastfeeding, smoking, following special diets 3 months before the study, taking chemical or herbal weight loss drugs, taking hepatotoxic drugs, taking blood pressure control drugs and blood lipid-lowering drugs

Intervention groups

Participants will be divided into two groups of 30 people: intervention group (1 capsule containing 10 mg boron

citrate per day before lunch) and placebo group (1 capsule per day of maltodextrin before lunch) and will use the supplement or placebo for 12 weeks.

Main outcome variables

glucose-insulin-HbA1c-insulin resistance with HOMA-IR score, lipid pattern, systolic and diastolic blood pressure) CRP, TNF- α , IL-10, and IL-6

General information

Reason for update

Delay in obtaining the necessary financial credit to start the project

Acronym

IRCT registration information

IRCT registration number: **IRCT20220806055624N1**

Registration date: **2022-08-31, 1401/06/09**

Registration timing: **prospective**

Last update: **2024-08-29, 1403/06/08**

Update count: **3**

Registration date

2022-08-31, 1401/06/09

Registrant information

Name

Helda Tutunchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete**Funding source****Expected recruitment start date**

2023-06-20, 1402/03/30

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of boron citrate supplementation on nutritional status, cardiometabolic factors, and inflammatory indices of TNF- α , IL-10, IL-6, and CRP and serum level of thyroid hormones and oxidative stress indices of SOD, PAB, GPx, TAC and gene expression of TNF- α , IL-10, IL-6, CRP, PPAR- γ , SIRT1, PGC-1 α , AMPK in obese people

Public title

Boron citrate in obesity

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

BMI: 30–40 (kg/m²) Willingness to participate in the study

Exclusion criteria:

Athlete, pregnancy, lactation and menopause in women Under infertility treatment, taking birth control pills and estrogen Smoking and history of alcohol consumption Following a special diet three months before the study Use of chemical or herbal drugs for weight loss and use of hepatotoxic drugs such as phenytoin, amoxifene, lithium, blood pressure control drugs and blood lipid lowering drugs (statins), drugs that increase insulin sensitivity. Taking antibiotics or supplements affecting liver enzyme levels Weight loss surgery in the last year or strict weight loss diets in the last three months Using corticosteroid and non-steroidal anti-inflammatory drugs and any supplements for 3 months before the study or during the study Cardiovascular diseases, liver, kidney, intestinal, thyroid and parathyroid dysfunction, biliary disease, known autoimmune diseases, polycystic ovary syndrome, cancers and malabsorption diseases such as sprue and Crohn's Having symptoms of infectious or inflammatory disease or recent surgery Performed or candidate for liver transplant

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To stratify individuals into distinct strata and blocks, stratified block randomization will be implemented based on age (18-40 vs. 40-60 years) and gender (male vs. female). For each individual placed in a given stratum, a matched individual is considered based on these variables in the same stratum. As a result, two participants with similar characteristics (for age and gender) are placed in the same stratum. Finally, each stratum will be randomly allocated to the intervention or control groups using Random Allocation Software (RAS). Participants and researchers will be blinded to the randomization and allocation until the end of the study. The randomization list will be provided by the pharmacist of the research center at the end of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and researchers will be blind to the type of supplements (boron citrate or placebo). The person responsible for preparing the supplement packages (a person completely unrelated to the study) will be asked to assign a three-digit code to each of the two received supplements (boron citrate or placebo) and keep the codes for himself until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

The specialized committee of ethics in biomedical research

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Daneshgah street

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Tabriz

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East Azarbaijan

Postal code

5165665811

Approval date

2022-07-11, 1401/04/20

Ethics committee reference number

IR.TBZMED.REC.1401.350

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Weight

Timepoint

Beginning and end of the trial

Method of measurement

Weight scale

2

Description

Body mass index (BMI)

Timepoint

Beginning and end of the trial

Method of measurement

Calculation based on formula

3

Description

Waist circumference (WC)

Timepoint

Beginning and end of the trial

Method of measurement

Tape measure

4

Description

Waist to hip ratio (WHR)

Timepoint

Beginning and end of the trial

Method of measurement

Calculation based on formula

5

Description

Waist to height ratio (WHtR)

Timepoint

Beginning and end of the trial

Method of measurement

Calculation based on formula

6

Description

C-reactive protein (CRP)

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

7

Description

Tumor necrosis factor- α (TNF- α)

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

8

Description

Interleukin-10 (IL-10)

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

9

Description

Interleukin-6 (IL-6)

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

10

Description

Hip circumference (HC)

Timepoint

Beginning and end of the trial

Method of measurement

Tape measure

Secondary outcomes

1

Description

Fasting blood sugar (FBS)

Timepoint

Beginning and end of the trial

Method of measurement

Use of an enzymatic kit method

2

Description

Fasting insulin levels

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

3

Description

Insulin resistance with HOMA-IR score

Timepoint

Beginning and end of the trial

Method of measurement

Calculation based on formula

4

Description

Low density lipoprotein cholesterol (LDL-c)

Timepoint

Beginning and end of the trial

Method of measurement

Calculation based on the Friedewald formula

5

Description

High density lipoprotein cholesterol (HDL-c)

Timepoint

Beginning and end of the trial

Method of measurement

Use of an enzymatic kit method

6

Description

Total cholesterol (TC)

Timepoint

Beginning and end of the trial

Method of measurement

Use of an enzymatic kit method

7

Description

Triglyceride (TG)

Timepoint

Beginning and end of the trial

Method of measurement

Use of an enzymatic kit method

8

Description

Systolic blood pressure (SBP)

Timepoint

Beginning and end of the trial

Method of measurement

Mercury manometer

9

Description

Diastolic blood pressure (DBP)

Timepoint

Beginning and end of the trial

Method of measurement

Mercury manometer

10

Description

Quantitative insulin sensitivity check index (QUICKI)

Timepoint

Beginning and end of the trial

Method of measurement

Calculation based on formula

11

Description

Serum level of triiodothyronine (T3)

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

12

Description

Serum level of tetraiodothyronine (T4)

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

13

Description

Serum level of thyroid Stimulating hormone (TSH)

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

14

Description

Prooxidant - Antioxidant balance (PAB)

Timepoint

Beginning and end of the trial

Method of measurement

ELISA

15

Description

Superoxide dismutase (SOD)

Timepoint

Beginning and end of the trial

Method of measurement

Spectrophotometric method and the Randox kit

16

Description

Glutathione Peroxidase (GPX)

Timepoint

Beginning and end of the trial

Method of measurement

Spectrophotometric method and the Randox kit

17

Description

Total antioxidant capacity (TAC)

Timepoint

Beginning and end of the trial
Method of measurement
Spectrophotometric method and the Randox kit

18

Description
Gene expression of CRP
Timepoint
Beginning and end of the trial
Method of measurement
Real-Time polymerase chain reaction (PCR) method

19

Description
Gene expression of TNF- α
Timepoint
Beginning and end of the trial
Method of measurement
Real-Time polymerase chain reaction (PCR) method

20

Description
Gene expression of IL-6
Timepoint
Beginning and end of the trial
Method of measurement
Real-Time polymerase chain reaction (PCR) method

21

Description
Gene expression of IL-10
Timepoint
Beginning and end of the trial
Method of measurement
Real-Time polymerase chain reaction (PCR) method

22

Description
Gene expression of AMPK
Timepoint
Beginning and end of the trial
Method of measurement
Real-Time polymerase chain reaction (PCR) method

23

Description
Gene expression of PPAR- γ
Timepoint
Beginning and end of the trial
Method of measurement
Real-Time polymerase chain reaction (PCR) method

24

Description
Gene expression of SIRT1
Timepoint
Beginning and end of the trial

Method of measurement
Real-Time polymerase chain reaction (PCR) method

25

Description
Gene expression of PGC-1 α
Timepoint
Beginning and end of the trial
Method of measurement
Real-Time polymerase chain reaction (PCR) method

26

Description
Total body fat mass (FM)
Timepoint
Beginning and end of the trial
Method of measurement
Bioelectrical impedance analysis

27

Description
Total body fat free mass (FFM)
Timepoint
Beginning and end of the trial
Method of measurement
Bioelectrical impedance analysis

Intervention groups

1

Description
Intervention group: Patients in this group will receive dietary recommendations and boron citrate capsules including 10 mg boron for 12 weeks. Boron citrate capsules is made in Iran, and once a day before lunch will be consumed.

Category
Prevention

2

Description
Control group: Patients in this group will receive dietary recommendations with placebo for 12 weeks. The placebo is starch (containing 10 mg of maltodextrin) and once a day before lunch will be consumed.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Nutrition Research Center of Tabriz University of Medical Sciences
Full name of responsible person

Helda Tutunchi

Street address

Nutrition faculty, Tabriz University of Medical Science,
Golgashat Avenue, Attar Neyshabouri Street

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5166614711

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+98 914 116 3184

Email

helda.nutrition@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

Street address

Tabriz University of Medical Sciences, Attar
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5166614711

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parvizshahabi@gmail.com

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

Helda Tutunchi

Position

Assistant Professor of Nutritional Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Tabriz University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor of Nutritional Sciences

Latest degree

Ph.D.

Other areas of specialty/work

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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

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 institutions.

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

The researchers (student and her supervisor)

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

Request a document via email

Comments