Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of boron citrate supplementation on the thyroid hormones and expression of PPAR-γ, SIRT1, PGC-1α, and AMPK genes in obese subjects: a double-blind randomized controlled clinical trial

Protocol summary

Study aim

The current study will be conducted with the aim of investigating the effect of boron citrate supplementation on the thyroid hormones and expression of PPAR-γ, SIRT1, PGC-1α and AMPK genes in obese people.

Design

This study will be done on sixty obese patients of both genders.

Settings and conduct

The study will be conducted in the Nutrition Research Center of Tabriz University of Medical Sciences and supplementation duration will be 12 weeks. The boron citrate and placebo packs will be coded by the person responsible for preparing them, and the main investigators and the patients will be blinded to the type of the supplements.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults aged between 18-60 years and with a body-mass index of 30 to 40 kg/m2. Exclusion criteria: Individuals who are smokers, those consuming alcohol, taking chemical or herbal drugs for weight loss, hepatotoxic drugs, anti-hypertensive drugs, lipid-lowering and anti-diabetic drugs, corticosteroid, and non-steroidal anti-inflammatory drugs and antibiotics will not be included. We also will not include individuals who are pregnant, lactating, menopause, and those who use birth control pills and estrogen. Individuals who have some pathologic conditions such as cardiovascular, liver, thyroid, parathyroid, kidney, gastrointestinal tract and autoimmune diseases as well as suffering from polycystic ovary syndrome, cancer and inflammatory disease will be excluded. Also, those who underwent weight loss surgery in the last year or weight loss diets in the last three months will not be included in the study.

Intervention groups

Patients in the boron citrate group will take one capsule containing 10 mg of boron daily. In the placebo group, one capsule containing 10 mg of maltodextrin will be consumed daily.

Main outcome variables

Expression of PPAR-γ, SIRT1, PGC-1α, and AMPK genes

General information

Reason for update

Adding secondary outcomes

Acronym

IRCT registration information

IRCT registration number: **IRCT20090609002017N36**
Registration date: **2023-03-19, 1401/12/28**
Registration timing: **prospective**

Last update: **2024-08-27, 1403/06/06**
Update count: **1**

Registration date

2023-03-19, 1401/12/28

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

2023-11-25, 1402/09/04

Expected recruitment end date

2024-05-24, 1403/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of boron citrate supplementation on the thyroid hormones and expression of PPAR-γ, SIRT1, PGC-1α, and AMPK genes in obese subjects: a double-blind randomized controlled clinical trial

Public title

Assessment of the effect of boron citrate supplementation in the prevention and treatment of obesity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Ages between 18 to 60 years body mass index (BMI) 30 to 40 kg/m2 Residence in Tabriz

Exclusion criteria:

Smokers Consuming alcohol Individuals taking chemical or herbal drugs for weight loss, hepatotoxic drugs, anti-hypertensive drugs, lipid-lowering and anti-diabetic drugs, corticosteroid, and non-steroidal anti-inflammatory drugs and antibiotics. Individuals who are pregnant, lactating, menopause, and those who use birth control pills and estrogen Individuals who have some pathologic conditions such as cardiovascular, liver, thyroid, parathyroid, kidney, gastrointestinal tract and autoimmune diseases as well as suffering from polycystic ovary syndrome, cancer and inflammatory disease Individuals who underwent weight loss surgery in the last year or weight loss diets in the last three months

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

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 separation of groups until the end of the study and data analysis. 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 and data analyses.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Tabriz University of Medical Sciences

Street address

Third Floor, Central Building (2), Tabriz University of Medical Sciences, Golghasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

00984133344280

Approval date

2022-12-26, 1401/10/05

Ethics committee reference number

IR.TBZMED.REC.1401.881

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
PPAR-γ gene expression
Timepoint
The beginning and end of the study
Method of measurement
Measurement of gene expression by RT-PCR method

2

Description
SIRT1 gene expression
Timepoint
The beginning and end of the study
Method of measurement
Measurement of gene expression by RT-PCR method

3

Description
PGC-1α gene expression
Timepoint
The beginning and end of the study
Method of measurement
Measurement of gene expression by RT-PCR method

4

Description
AMPK gene expression
Timepoint
The beginning and end of the study
Method of measurement
Measurement of gene expression by RT-PCR method

Secondary outcomes

1

Description
Serum level of triiodothyronine (T3)
Timepoint
The beginning and end of the study
Method of measurement
ELISA

2

Description
Serum level of tetraiodothyronine (T4)
Timepoint
The beginning and end of the study
Method of measurement
ELISA

3

Description
Serum level of thyroid Stimulating hormone (TSH)
Timepoint
The beginning and end of the study
Method of measurement
ELISA

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
Alireza Ostadrahimi
Street address
Attar Neyshabouri Street, Golgasht Avenue, Nutrition faculty, Tabriz University of Medical Science, Ground Floor
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ostadrahimi@tbzmed.ac.ir

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 Neishabouri Street, Golgasht Avenue

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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
Dr. Alireza Ostadrahimi

Position
Professor of Nutritional Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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Professor of Nutritional Sciences

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Person responsible for updating data

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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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

Data will be available 12 months after manuscript 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