

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of boron citrate supplementation on the thyroid hormones and expression of PPAR- γ , SIRT1, PGC-1 α , 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-1 α 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-1 α , 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)

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Email address

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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	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.
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	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.
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	Placebo Used Assignment Parallel Other design features Secondary Ids empty
Age From 18 years old to 60 years old Gender Both Phase N/A Groups that have been masked - Participant - Investigator	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
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	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-1 α 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

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Tabriz University of Medical Sciences, Attar
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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. Alireza Ostadrahimi

Position

Professor of Nutritional Sciences

Latest degree

Ph.D.

Other areas of specialty/work

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

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