

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of simultaneous oral supplementation with branched chain amino acids and vitamin B6 on body composition, insulin resistance index, serum lipid profile, lipocalin-2 and interleukin-18 in overweight and class1 obese women receiving hypocaloric diet.

Protocol summary

Summary

This study aims to investigate the effect of simultaneous oral supplementation with branched chain amino acids and vitamin B6 on body composition, insulin resistance index, serum lipid profile, lipocalin-2 and interleukin-18 in overweight and class1 obese women receiving hypocaloric diet. The study population includes Urmia overweight and class1 obese women which are volunteer for receiving hypocaloric diet. 42 person randomly divide into intervention and placebo groups. This study is a Controlled, Randomized, double-blind clinical trial and Block Randomization will be used. In a one month duration, intervention goes on and before and after intervention thorough blood sampling insulin resistance index, serum lipid profile, lipocalin-2 and interleukin-18 will be checked and compared and also body composition with the use of BIA before and after and during the intervention will be measured. Participant with BMI=25-35 should not use the any diet program and supplement, they shouldn't suffer any special disease condition. The intervention group will receive hypocaloric diet plus BCAA caplets and vitamin B6 pills and the placebo group will receive hypocaloric diet plus placebo caplets and pills. Primary outcomes includes body composition, insulin resistance index, serum lipid profile, lipocalin-2 and interleukin-18 and secondary outcome is Waist-to-hip ratio.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042813678N12**

Registration date: **2016-06-29, 1395/04/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-29, 1395/04/09

Registrant information

Name

Saeed Ghavamzadeh

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 1278 0803

Email address

ghavamzadeh_s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Urmia University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of simultaneous oral supplementation with branched chain amino acids and vitamin B6 on body composition, insulin resistance index, serum lipid profile, lipocalin-2 and interleukin-18 in overweight and class1

obese women receiving hypocaloric diet.

Public title
The effect of branched chain amino acids and vitamin B6 on weight loss

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: female, Childbearing age, BMI=25-35 kg/m², no pregnancy or lactation, absence of endocrinal, thyroid, metabolic and intestinal diseases and diabetes, no follow of specific diet, no follow of heavy sports, no change in cigarettes and caffeine consumption pattern during 4 weeks before study lunch, no weight loss more than 4.5 kg during 2 month before study lunch, no use of any supplementation and eight loss drugs and OCP during and 4 weeks before study, no significant weight change one week before study lunch. Exclusion criteria: any drug or diet side effects, unwillingness to continue the study, pregnancy, menopause, physical activity and diet changes, diseases.

Age
From **13 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The block randomization method is designed to randomize subjects into groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd, Urmia

City

Urmia

Postal code

5714783734

Approval date

2016-04-06, 1395/01/18

Ethics committee reference number

ir.umsu.rec.1395.2

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

2

Description of health condition studied

overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

body composition

Timepoint

before intervention, 2 weeks after intervention and after intervention

Method of measurement

BIA analyzer

2

Description

Insulin resistance index

Timepoint

before and after intervention

Method of measurement

HOMA-IR formula

3

Description

lipocalin-2

Timepoint

before and after intervention

Method of measurement

ng/l- Serum samples test

4

Description

interleukin-18

Timepoint

before and after intervention

Method of measurement

ng/l- Serum samples test

5

Description

lipid profile

Timepoint

before and after intervention

Method of measurement

Serum samples test

Secondary outcomes

1

Description

Waist-hip ratio

Timepoint

before and after intervention

Method of measurement

tape measure

Intervention groups

1

Description

BCAA caplets, 1 gr, 3 times a day , 2 caplets each time, for a month

Category

Treatment - Drugs

2

Description

placebo caplets of BCAA, 1 gr, 3 times a day, 2 caplets each time, for a month

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Khomeini Hospital of Urmia

Full name of responsible person

zahra shakibaie novin

Street address

Imam Khomeini University Hospital-ershad Ave-
Modarres Blvd-Urmia-Iran

City

Urmia

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor for research of Urmia University of
Medical Sciences

Full name of responsible person

Dr Iraj Mohebbi

Street address

Orjhans Street, Resalat Blvd, Urmia , Iran

City

Urmia

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Urmia University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Urmia University of Medical Sciences

Full name of responsible person

Dr Saied Ghavamzadeh

Position

Associate Professor/Nutritional Sciences PhD

Other areas of specialty/work**Street address**

Pardis Nazlou, 11 km of Nazlou Road,Urmia,Iran

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+98 44 3278 0803

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Urmia University of Medical Sciences

Full name of responsible person

Dr Saied Ghavamzadeh

Position

Nutritional Sciences PhD/Associate Professor

Other areas of specialty/work

Street address

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City

Urmia

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty