Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 hypo caloric diet. The study population includes Urmia overweight and class1 obese women which are volunteer for receiving hypo caloric 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 hypo caloric diet plus BCAA caplets and vitamin B6 pills and the placebo group will receive hypo caloric 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)

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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 interventioin
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
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Person responsible for updating data

Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person

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Position
Nutritional Sciences PhD/Associate Professor
Other areas of specialty/work
Street address
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City
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Phone
00
Fax
Email
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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