Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effect of oral taurine supplementation on Serum levels of fibroblast growth factors (FGF19, FGF21), β-Klotho co-receptor, glycemic status, lipid profile, adipocytokines, hs-CRP and body composition in obese women on a weight-loss diet

Protocol summary

Study aim

Determine the effect of oral taurine supplementation on serum levels of fibroblast growth factors (FGF19, FGF21), β-Klotho co-receptor, glycemic status, lipid profile, adipocytokines, hs-CRP and body composition

Design

This is a double-blind, parallel-group, randomized controlled clinical trial

Settings and conduct

This study will be carried out by referring to private nutrition clinics in Ahvaz city. Individuals in the intervention and control group will receive 3 grams of Taurine daily in the form of capsules or placebo for 2 months, respectively. Each person will fill the individual consent, physical activity and 24-hour recall questionnaires. At the beginning and the end of the study, fasting blood samples are taken from 5 mL blood donors. energy needs will calculate by Mifflin Jeor St equation. Then, 30% of estimated energy requirements will deduct.

Participants/Inclusion and exclusion criteria

Eligibility criteria: women aged 18 to 50 years old and body mass index (BMI) between 30 to 40; Non eligibility criteria: menopause, pregnancy and breastfeeding, having history of food allergy, cancer, acute or chronic renal failure, acute or chronic hepatic failure, thyroid disorder and gastrointestinal diseases, having surgical operation for weight loss, having weight loss over the past six months ,consumption of multivitamin/mineral or herbal supplements and weight-loss drugs,having a special diet.

Intervention groups

1) placebo group + a standard hypocaloric diet 2) taurine supplementation group + a standard hypocaloric diet

Main outcome variables

FGF19, FGF21, β-Klotho co-receptor, glycemic status, lipid profile, adipocytokines, hs-CRP and body composition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131125015542N2**
Registration date: **2018-11-24, 1397/09/03**
Registration timing: **prospective**

Last update: **2018-11-24, 1397/09/03**
Update count: **0**

Registration date

2018-11-24, 1397/09/03

Registrant information

Name

Maryam Asadi

Name of organization / entity

Ahvaz jundi shapoor university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8253

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-05, 1397/09/14

Expected recruitment end date

2020-12-04, 1399/09/14

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of oral taurine supplementation on Serum levels of fibroblast growth factors (FGF19, FGF21), β-Klotho co-receptor, glycemic status, lipid profile, adipocytokines, hs-CRP and body composition in obese women on a weight-loss diet

Public title
Effect of Taurine in obesity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 18 to 50 years old Body mass index between 30 to 40
Exclusion criteria:
Pregnancy and breast feeding Menopause Food allergy Having surgical operation to weight loss Having weight loss over the past six months Consumption of multivitamin/mineral supplements, herbal supplements or weight-loss drugs Having a special diet Having a history of cancer, acute or chronic renal Failure, acute or chronic hepatic failure, thyroid disorder and gastrointestinal diseases
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible subjects will be divided randomly into two groups including control and intervention. Randomization will be performed using the computer-generated random numbers. the naming of taurine or placebo bottles will be done based on random numbers and odd or even numbers will be allocated to the A or B group. To achieve allocation concealment, the bottles will be sealed and we will be assured from the similarity of appearance and their weight. The randomization process will be performed by an individual other than the investigators to reduce the probable bias.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding will be done in the case of participants and the main investigator. For blinding, placebo capsules will be prepared in the same size, shape, bottle with taurine capsules. Bottles will be encoded A or B. Also, the researcher is unaware of the type of capsules. Therefore, that participants and researcher will be blinded at the selection step and information collection.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundi shapur University of Medical Sciences
Street address
Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2018-11-10, 1397/08/19
Ethics committee reference number
IR.AJUMS.REC.1397.590

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
Serum level of fibroblast growth factors FGF19
Timepoint
Before and 8 months after intervention
Method of measurement
ELISA

2

Description
Serum level of fibroblast growth factors FGF21

Timepoint
Before and 8 months after intervention
Method of measurement
ELISA

3

Description
Serum level of β-Klotho co-receptor
Timepoint
Before and 8 months after intervention
Method of measurement
ELISA

4

Description
Serum level of leptin
Timepoint
Before and 8 months after intervention
Method of measurement
ELISA

5

Description
Serum level of adiponectin
Timepoint
Before and 8 months after intervention
Method of measurement
ELISA

6

Description
Serum level of High sensitivity C-reactive protein (hs-CRP)
Timepoint
Before and 8 months after intervention
Method of measurement
ELISA

7

Description
Serum level of insulin
Timepoint
Before and 8 months after intervention
Method of measurement
ELISA

8

Description
Lipid profile
Timepoint
Before and 8 months after intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

9

Description
Alanine transaminase, Aspartate transaminase and Gamma-glutamyltransferase
Timepoint
Before and 8 months after intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

10

Description
Body composition
Timepoint
Before, 4 weeks and 8 weeks after intervention
Method of measurement
Bioelectrical impedance analysis

11

Description
Waist circumference
Timepoint
Before, 4 weeks and 8 weeks after intervention
Method of measurement
Tape metre

12

Description
Fasting blood sugar (FBS)
Timepoint
Before and 8 months after intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

13

Description
Body weight
Timepoint
Before, 4 weeks and 8 weeks after intervention
Method of measurement
Scale

14

Description
Homeostatic Model Assessment for Insulin Resistance (HOMA-IR)
Timepoint
Before and 8 months after intervention
Method of measurement
HOMA-IR: [fasting insulin Mu/ml × fasting glucose mg/dl]/405

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Daily consumption of 3 gram taurine

(cap 1 gram) simultaneously with weight loss diet for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Daily consumption of 3 cap placebo simultaneously with weight loss diet for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Majid Mohammadshahi s Diet Therapy Clinic

Full name of responsible person

Maryam Asadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Ahvaz 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Maryam Asadi

Position

Ph.D. student of nutrition sciences

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Haidari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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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
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Publication of protocol study in form of the article and also data publication in the original article. The total potential data can be shared after unidentifiable subjects.
When the data will become available and for how long
6 months after the publication of results
To whom data/document is available
All researchers who have access to clinical trials databases
Under which criteria data/document could be used
The only way for using the data is after the publication of the article in the indexed ISI journal.
From where data/document is obtainable
Via database websites such as PubMed and google scholar and via email address: maryamasadi136@gmail.com
What processes are involved for a request to access data/document
The original article reaches the requestor by email within a maximum of one week.
Comments