

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)

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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

AgeFrom **18 years** old to **50 years** old**Gender**

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget 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

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Golestan Blvd

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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 $\times$ 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
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Sponsors / Funding sources

1

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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
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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