

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of taurine supplementation on serum levels of adiponectin, irisin, fibroblast growth factor-21, sirtuin-1, metabolic parameters, oxidative, inflammatory indicators and nutritional status in patients with type 2 diabetes

Protocol summary

Study aim

To determine the supplementation effect of taurine on serum levels of adiponectin, irisin, fibroblast growth factor-21, sirtuin-1, metabolic parameters, oxidative, inflammatory indicators and nutritional status in patients with type 2 diabetes

Design

Randomized double-blind clinical trial with two arm parallel groups phase 3 trial

Settings and conduct

The trial will be conducted at outpatient cardiology clinic of Imam Reza center affiliated to Tabriz University of Medical Sciences, Iran. All the patients will be screened by an expert endocrinologist for eligibility. Those willing to take part in the study will be carefully evaluated with reference to inclusion criteria. Then, they will be requested to sign an informed consent. A third party who is blind to the study will give the sequence extracted from allocation software. After an overnight fasting, blood will be collected and supplements will be provided to the participants. supplementation duration will be 8 weeks.

Participants/Inclusion and exclusion criteria

46 patients with type 2 diabetes are included in the study. Patients with cardiovascular, renal, hepatic, hypothyroidism, and hyperthyroidism and those who have received supplementary foods in the last 3 months will not be included in the study.

Intervention groups

Intervention group: will consume 3 milliliters of Turin capsules daily. (placebo) control group: Take 3 capsules containing maltodextrin daily.

Main outcome variables

Serum levels of adiponectin, irisin, fibroblast growth factor-21, sirtuin-1, metabolic parameters, oxidative, inflammatory indicators and nutritional status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121028011288N16**

Registration date: **2019-02-08, 1397/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-15, 1398/01/26**

Update count: **1**

Registration date

2019-02-08, 1397/11/19

Registrant information

Name

Mohammad Alizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7313

Email address

mdalizadeh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-04-22, 1398/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of taurine supplementation on serum levels of adiponectin, irisin, fibroblast growth factor-21, sirtuin-1, metabolic parameters, oxidative, inflammatory indicators and nutritional status in patients with type 2 diabetes

Public title

Taurine in type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Type 2 Diabetes Patients who use glucose lowering oral medications are well controlled by their blood glucose levels. Body mass index 35-25 kg /m² will be included in the study. age range from 30-60 years

Exclusion criteria:

Use of multi-vitamin and mineral supplements over the past 3 months. Taking corticosteroids and non-steroidal anti-inflammatory drugs. Taking insulin Patients with polycystic ovary syndrome Patients with chronic diseases such as cardiovascular, renal and hepatic disorders, and hypothyroidism and hyperthyroidism Having certain physiological conditions such as pregnancy and lactation.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible participants will be randomly allocated to intervention and placebo groups using a software generated random permuted blocks. The generated random sequence will be kept in a protected location and administered by an independent third party who is blind to the trial throughout the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, no patient and investigator will be aware of the treatment assignments for the duration of the study. For blinding the trial, the taurine capsules and placebo, will be identical in appearance, packaging, and labeling. All capsules will be packed and encoded by the company (karenCompany).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Attar Neyshabouri Av., Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166/15731

Approval date

2018-11-19, 1397/08/28

Ethics committee reference number

IR.TBZMED.REC.1397.682

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Level of adiponectin

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of adiponectin via ELISA kit

2**Description**

Level of irisin

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of irisin via ELISA kit

3**Description**

Level of fibroblast growth factor-21 (FGF-21)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of fibroblast growth factor-21 (FGF-21) via ELISA kit

4

Description

Level of sirtuin-1

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of sirtuin-1 via ELISA kit

5

Description

Level of fasting blood sugar (FBS)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of fasting blood sugar (FBS) by enzymatic method

6

Description

Level of insulin

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of insulin by enzymatic method

7

Description

Level of hemoglobin A1C

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of hemoglobin A1C by enzymatic method

8

Description

HOMA-IR scores

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of HOMA-IR score using formula.

9

Description

Serum level of total cholesterol (TC)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of total cholesterol (TC) level via enzymatic kit

10

Description

Serum level of triglyceride

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of triglyceride (TG) level via enzymatic kit

11

Description

Serum level of HDL

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of HDL level via enzymatic kit

12

Description

Serum level of LDL

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of LDL using friedewald equation

13

Description

Serum level of total antioxidant capacity (TAC)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of total antioxidant capacity (TAC) by spectrophotometry

14

Description

Serum level of malondialdehyde (MDA)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of malondialdehyde (MDA) by spectrophotometry

15

Description

Serum level of catalase

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of catalase by spectrophotometry

16

Description

Serum level of superoxide dismutase (SOD)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of superoxide dismutase (SOD) by

spectrophotometry

17

Description

Serum level of TNF-a

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of TNF-a via ELISA kit

18

Description

Serum level of interleukin-6 (IL-6)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of interleukin-6 (IL-6) via ELISA kit

19

Description

Serum level of hs-CRP

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of hs-CRP via ELISA kit

Secondary outcomes

1

Description

Assessment of the body composition

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Assess body composition using the body composition analyzer

2

Description

Physical activity level

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Via IPAQ questionnaire

3

Description

Assessment of dietary intake

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

3-day food record

Intervention groups

1

Description

Intervention group: Patients in this group will receive 3 capsules of 1000 milligrams of taurine (product by karen Co. and made in The Iran) for 8 weeks a day.

Category

Treatment - Drugs

2

Description

Control group: Control group: Patients in this group will receive maltodextrin capsules for 8 weeks which are same size and shape (product by karen Co. and made in The Iran) and used once a day with lunch.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Medical Research & Training Hospital

Full name of responsible person

Dr. Mohammad Alizadeh

Street address

Daneshgah street, Imam Reza Medical Research Training Center

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 7581

Fax

+98 41 3334 0634

Email

mdalizadeh@tbzmed.ac.ir

Web page address

<http://nutr.tbzmed.ac.ir/?PageID=128&ID=37&BasesID=140>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Juyban

Street address

Vice Chancellor for Research No 2 Central Building, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 7581

Fax**Email**

mdalizadeh@tbzmed.ac.ir

Web page address

http://nutr.tbzmed.ac.ir

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

Vahid Maleki

Position

Ph.D. candidate of nutrition sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Golgashat street, Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3381 1902

Email

malekivahid433@yahoo.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Alizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Golgashat street, Tabriz university of medical sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 7581

Email

mdalizadeh@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Alizadeh

Position

استاد راهنما، دانشیار

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Golgashat street, Tabriz university of medical sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 1335 7313

Email

mdalizadeh@tbzmed.ac.ir

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

Undecided - It is not yet known if there will be 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

Data collected for the primary outcomes will be shared.

When the data will become available and for how long

Accessibility to data is possible 8 months after 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

Dr. Mohammad Alizadeh, Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences Email: mdalizadeh@tbzmed.ac.ir 0098 9141894102

What processes are involved for a request to access data/document

The applicator can send a request to the person responsible for the study by email and within 10 days the document will be sent to the requesting person.

Comments