

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of taurine supplementation on serum levels of endothelial markers, metabolic parameters, adipokines, inflammatory and glycemic 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 endothelial markers, metabolic parameters, adipokines, inflammatory and glycemic 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 Kermanshah 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

120 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 endothelial markers, metabolic parameters, adipokines, inflammatory and glycemic indicators and nutritional status in patients with type 2 diabetes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180712040438N3**

Registration date: **2020-02-26, 1398/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-26, 1398/12/07**

Update count: **0**

Registration date

2020-02-26, 1398/12/07

Registrant information

Name

Jalal Moludi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 2148

Email address

jmoludi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-31, 1398/11/11

Expected recruitment end date

2020-03-21, 1399/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of taurine supplementation on serum levels of endothelial markers, metabolic parameters, adipokines, inflammatory and glycemic indicators and nutritional status in patients with type 2 diabetes

Public title

Effect of Taurine in treatment of 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
- Care provider
- Investigator

Sample size

Target sample size: **120**

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 Kermanshah University of Medical Sciences

Street address

Faculty of Nutrition and Food Technology, Next to Farabi Hospital, Kermanshah, Iran , Postcode: 6719851552

City

Kermanshah

Province

Kermanshah

Postal code

6719851552

Approval date

2020-02-22, 1398/12/03

Ethics committee reference number

IR.KUMS.REC.1398.1187

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

endothelial markers (ICAM, VCAM)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement via ELISA kit

2

Description

Level of Adiponektin

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement via ELISA kit

3

Description

Serum level of hs-CRP

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement via ELISA kit

4**Description**

Serum level of IL-6

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement via ELISA kit

5**Description**

Serum level of MM9,3

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement via ELISA kit

6**Description**

Serum level of Visfastin

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement via ELISA kit

7**Description**

Serum level of Glycemic index

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement via ELISA kit

8**Description**

Serum level of Leptien

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement via ELISA kit

9**Description**

Serum level of Total antioxidant capacity

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement via ELISA kit

10**Description**

Serum level of Plasminogen activator inhibitor (PAL)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement via ELISA kit

11**Description**

Serum level of Tissue plasminogen activator (tPA)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement via ELISA kit

Secondary outcomes**1****Description**

eGFR Assessment of the health-related quality of life (HRQOL)

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Via HRQOL questionnaire

2**Description**

Assessment of the Estimated Glomerular Filtration Rate (eGFR)

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Using serum creatinine level

Intervention groups**1****Description**

Intervention group: 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

Placebo

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. Jalal Moludi
Street address
Imam Reza Medical Research & Training Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Krmanshah University of Medical Sciences
Street address
Vice Chancellor for Research No 2 Central Building,
Kermanshah University of Medical Sciences, Beheshti
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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

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
Kermanshah University of Medical Sciences
Full name of responsible person
Jalal Moludi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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. Jalal Mokudi, Faculty of Nutrition and Food Sciences, Kermanshah University of Medical Sciences Email: jmoludi@yahoo.com 0098 9399516760

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