Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 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 /m 2 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
City
Kermanshah
Province
Kermanshah
Postal code
5125814711
Phone
+98 21 8670 5503
Email
jmoludi@yahoo.com

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 Street, Tabriz
City
Krmanshah
Province
Kermanshah
Postal code
2589631478
Phone
+98 83 8380 2009
Email
jmoludi@yahoo.com
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
Street address
Isar St
City
Tabriz
Province
Kermanshah
Postal code
1235648952
Phone
+98 41 3335 2148
Fax
+98 41 3335 2148
Email
moludij@tbzmed.ac.ir

Person responsible for scientific 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
Street address
Isar St
City
Tabriz
Province
Kermanshah
Postal code
1234698745
Phone
+98 41 3335 2148
Fax
+98 41 3335 2148
Email
moludij@tbzmed.ac.ir

Person responsible for updating data

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

Street address

Isar St

City

Tabriz

Province

Kermanshah

Postal code

213548658

Phone

+98 41 3335 2148

Fax

+98 41 3335 2148

Email

moludij@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

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