Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effects of taurine supplementation on serum levels of pentosidine, soluble receptor of advanced glycation end products, methylglyoxal, glycemic, oxidative and nutritional status in patients with type 2 diabetes

Protocol summary

Study aim
To determine the supplementation effect of taurine on serum levels of pentosidine, soluble receptor of advanced glycation end products, methylglyoxal, 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
6 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 pentosidine, soluble receptor of advanced glycation end products, methylglyoxal, metabolic parameters, oxidative, inflammatory indicators and nutritional status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121028011288N17**
Registration date: **2019-02-28, 1397/12/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-28, 1397/12/09**
Update count: **0**

Registration date
2019-02-28, 1397/12/09

Registrant information

Name
Mohammad Alizadeh

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

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 effects of taurine supplementation on serum levels of pentosidine, soluble receptor of advanced glycation end products, methylglyoxal, glycemic, oxidative and nutritional status in patients with type 2 diabetes

Public title
taurine in 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 20-60 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
- Data analyser

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
2018-12-23, 1397/10/02
Ethics committee reference number
IR.TBZMED.REC.1397.752

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
pentosidine
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of pentosidin via ELISA kit

2

Description
soluble receptor of advanced glycation end products
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of soluble receptor of advanced glycation end products via ELISA kit

3

Description
methylglyoxal

Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of methylglyoxal 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
At the beginning of the study and 8 weeks later
Method of measurement
Via IPAQ questionnaire

3

Description
Assessment of dietary intake
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
3-day food record

4

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

5

Description
Level of insulin
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of insulin by enzymatic method

6

Description
Level of hemoglobin A1C
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of hemoglobin A1C by enzymatic method

7

Description
HOMA-IR scores
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of HOMA-IR score using formula.

8

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

9

Description
Serum level of triglyceride
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of triglyceride (TG) level via enzymatic kit

10

Description
Serum level of HDL
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of HDL level via enzymatic kit

11

Description
Serum level of LDL
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of LDL using friedewald equation

12

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

13

Description
Serum level of malondialdehyde (MDA)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of malondialdehyde (MDA) by

spectrophotometry

14

Description
Serum level of superoxide dismutase (SOD)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of superoxide dismutase (SOD) by spectrophotometry

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
Treatment - Drugs

2

Description
Control group: 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
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Daneshgah street, Imam Reza Medical Research Training Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Juyban
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Vice Chancellor for Research No 2 Central Building, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
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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
Tabriz University of Medical Sciences
Full name of responsible person
Fatemeh Esmaeili
Position
M.Sc student Of Clinical Nutrition
Latest degree
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Superviser, Professor, Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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
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