Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effect of carnosine supplementation on advanced glycation endproductsandtheir soluble reseptor, metabolic condition and oxidative indices in type2 diabetic patients

Protocol summary

Summary

The current Randomized double blind placebo controlled study will be conducted on type 2 diabetic patients with the aim of studing effect of carnosine supplementation on advanced glycation end productsandtheir soluble reseptor, metabolic condition and oxidative indices. 44 patients will randomly be allocated 2 groups: 1- study group (reciving carnosine) 2- control group(receiving placebo). Study group will receive daily 2 capsules of 500 mg carnosine for 3 month and control group will receive micro crystalline cellulose for 3 month.The questionnaires of general characters and food frequency will be completed by interview.Three days food record will be competed by patients. The biochemichal indices and Anthropometric measurements will be measured at baseline and at the end of the study. : will be measured

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011211689N2**
Registration date: **2016-02-01, 1394/11/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-02-01, 1394/11/12

Registrant information

Name

Sorayya Kheirouri

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

kheirouris@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of research and technology of Tabriz university of medical science

Expected recruitment start date

2016-02-04, 1394/11/15

Expected recruitment end date

2016-05-04, 1395/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of carnosine supplementation on advanced glycation endproductsandtheir soluble reseptor, metabolic condition and oxidative indices in type2 diabetic patients

Public title

The effect of carnosine supplementation in type 2 diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusuion criteria: : 1- Patients with type 2 diabetes age:30-60 2- patients using oral agents 3-BMI<40 Exclusion criteria: 1-BMI>40 2- inflammatory and alergic disease 3-menopause 4- use of multivitamine-mineral 3 month prior to the study 4- use of corton or anti inflammetory steroid drugs 4- change in dosage of bloos

sugar lowering drugs 5- chang in physical activity (duration and intensity) 6-use of insulin 7- patients affected with Poly cystic ovary syndrome 8-cardiovascular, kidney, liver disaese (exept fatty liver),9-hypo and hypertyroidism 9- Pregnency and lactation

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

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 science

Street address
Golgasht street/central bulilding/ 3th floor

City
Tabriz

Postal code

Approval date
2015-12-13, 1394/09/22

Ethics committee reference number
TBZMED.REC.1394.854

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
srume pentosidine

Timepoint
prior to the study and 3 month after

Method of measurement
ElISA

2

Description
Carboxymethyllysine

Timepoint
prior to the study and 3 month after

Method of measurement
ElISA

3

Description
sRAGE

Timepoint
prior to the study and 3 month after

Method of measurement
ElISA

4

Description
TG-Total cholestrol-LDL- HDL

Timepoint
prior to the study and 3 month after

Method of measurement
ElISA

5

Description
Fasting blood suger

Timepoint
prior to the study and 3 month after

Method of measurement
Enzymetic method

6

Description
Insuline

Timepoint
prior to the study and 3 month after

Method of measurement
ElISA

7

Description
HOMA score

Timepoint
prior to the study and 3 month after

Method of measurement

Insulin (mU/L) * FSG(mmol/L) /22.5

8

Description
HbA1c
Timepoint
prior to the study and 3 month after
Method of measurement
HPLC chromatography

9

Description
Total Antioxidant Capacity
Timepoint
prior to the study and 3 month after
Method of measurement
spectrophotometry

10

Description
malondialdehyde
Timepoint
prior to the study and 3 month after
Method of measurement
spectrophotometry

11

Description
superoxide dismutase
Timepoint
prior to the study and 3 month after
Method of measurement
spectrophotometry

12

Description
catalase
Timepoint
prior to the study and 3 month after
Method of measurement
spectrophotometry

13

Description
Nitric oxide
Timepoint
prior to the study and 3 month after
Method of measurement
spectrophotometry

14

Description
Protein carbonil
Timepoint
prior to the study and 3 month after
Method of measurement
spectrophotometry

Secondary outcomes

1

Description
systolic diastolic blood pressure
Timepoint
prior to the study and 3 month after
Method of measurement
Digital manometer

Intervention groups

1

Description
Carnosine capsule (500 mg, twice daily, totall dose of 1000 mg, for 3 month)
Category
Other

2

Description
placebo capsule (micro crystalline cellulose)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology clinic
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of research and technology of Tabriz university of medical science
Full name of responsible person
Mohammad Reza Rashidi
Street address
Golgasht street/central bulilding/ 3th floor
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of research and technology of Tabriz university of

medical science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz university of Medical science

Full name of responsible person

Shiva Hoojeghani

Position

PhD fellow of nutrition

Other areas of specialty/work

Street address

Golghasht street-Atter Neyshabouri avenue-Faculty of nutrition

City

Tabriz

Postal code

Phone

+98 41 3335 7581

Fax

Email

Shiva.hoojeghani@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz university of medical science-nutrition faculty

Full name of responsible person

Dr. Sorayya kheirouri

Position

PhD of nutrition- Associate Professor

Other areas of specialty/work

Street address

Golghasht street-Atter Neyshabouri avenue-Faculty of nutrition

City

Tabriz

Postal code

Phone

+98 41 3335 7580

Fax

Email

kheirouris@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Shiva Hoojeghani

Position

Other areas of specialty/work

Street address

Golghasht street-Atter Neyshabouri avenue-Faculty of nutrition

City

Postal code

Phone

00

Fax

Email

shiva.hoojeghani@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty