

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of carnosine supplementation on advanced glycation endproducts and their soluble receptor, metabolic condition and oxidative indices in type 2 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 studying effect of carnosine supplementation on advanced glycation end products and their soluble receptor, metabolic condition and oxidative indices. 44 patients will randomly be allocated 2 groups: 1- study group (receiving carnosine) 2- control group (receiving placebo). Study group will receive daily 2 capsules of 500 mg carnosine for 3 months and control group will receive micro crystalline cellulose for 3 months. The questionnaires of general characters and food frequency will be completed by interview. Three days food record will be completed by patients. The biochemical 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)

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+98 41 1335 7580

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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 end products and their soluble receptor, metabolic condition and oxidative indices in type 2 diabetic patients

Public title

The effect of carnosine supplementation in type 2 diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion 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 allergic disease 3-menopause 4- use of multivitamin-mineral 3 month prior to the study 4- use of corticosteroid or anti-inflammatory steroid drugs 4- change in dosage of blood

sugar lowering drugs 5- change in physical activity (duration and intensity) 6-use of insulin 7- patients affected with Poly cystic ovary syndrome 8- cardiovascular, kidney, liver disease (except fatty liver), 9- hypo and hyperthyroidism 9- Pregnancy 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 building/ 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

uric acid

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 cholesterol-LDL- HDL

Timepoint

prior to the study and 3 month after

Method of measurement

ELISA

5

Description

Fasting blood sugar

Timepoint

prior to the study and 3 month after

Method of measurement

Enzymatic 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, total 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 building/ 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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz university of medical science-nutrition faculty

Full name of responsible person

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Position

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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