

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effects of choline, magnesium and combined choline and magnesium supplementation on the components of inflammatory and coagulation markers in patients with type 2 diabetes mellitus

Protocol summary

Study aim

Determination and Comparison of the Effects of Cholin, Magnesium and Co-Choline and Magnesium on Components of Inflammatory and Coagulant factors in Type 2 Diabetic Patients

Design

parallel randomized controlled double blinded trial with a sample size of 80 people

Settings and conduct

The practical stages of the study are carried out in Tabriz . Patients with type 2 diabetes are selected with an endocrinologist diagnosis. Patients and researcher are blind.

Participants/Inclusion and exclusion criteria

Men and women with type 2 diabetes aged between 30-60 years. Patients who control their diabetes by glucose lowering tablets and do not use insulin.

Intervention groups

Qualified patients will be randomly divided into four groups of: 1- Choline supplement, 2- Magnesium supplement, 3- Co Choline and Magnesium, and 4- Placebo.

Main outcome variables

Inflammatory factors: IL-6, tPA coagulatory factors : tPA, PAI-1

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110123005670N25**

Registration date: **2018-03-09, 1396/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-09, 1396/12/18**

Update count: **0**

Registration date

2018-03-09, 1396/12/18

Registrant information

Name

Ali Tarighat-Esfanjeni

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 914 300 5895

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of choline, magnesium and combined choline and magnesium supplementation on the components of inflammatory and coagulation markers in patients with type 2 diabetes mellitus

Public title

The effects of combined choline and magnesium supplementation in patients with type 2 diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with type 2 diabetes Men and women aged 60-30 years Patients who their diabetes have been controlled by glucose lowering tablets BMI=25-35 kg/m2

Exclusion criteria:

Unwillingness to cooperate patients with inflammatory diseases, allergy, MS, kidney, liver, thyroid diseases Use of insulin and corticosteroids and non-steroidal anti-inflammatory drugs and hormonal products Changes in diet and physical activity, and type or dosage of medications used during the study Pregnancy and breastfeeding Tobacco and supplement use

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly divided into 4 groups of magnesium, choline, co-choline-magnesium and placebo supplementation. The packet method will be used for administering supplements and placebo to selected individuals; The randomization sequence is written in packets and will be delivered by a third person who is not aware of their content. So the investigator and the participants will not know which group they belong.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are unaware of the type of the intervention they receive. In order to blind patients, capsules identical to the supplements are prescribed for the control group. Each patient receive 3 capsules per day; group 1, one capsule of magnesium and two capsules of choline, group 2, 3 capsules of placebo, group 3, 1 magnesium capsule and two placebo capsules, and group 4, one placebo capsule and two capsules of choline. Also, a scientist who perform assessment of results and data analysis is also unaware of the type of the intervention each person receives.

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

Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2018-01-21, 1396/11/01

Ethics committee reference number

IR.TBZMED.REC.1396.945

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

Fast Blood Sugar

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

Enzymatic with Commercial Kits

2

Description

hemoglobin A1C

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

ELISA with Commercial Kits

3

Description

insulin

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

ELISA

4**Description**

Triglyceride

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

Enzymatic

5**Description**

Total Cholesterol

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

Enzymatic

6**Description**

HDL-Cholesterol

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

Enzymatic

7**Description**

LDL-Cholesterol

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

Enzymatic

8**Description**

Interleukin-6 (IL-6)

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

ELISA

9**Description**

vascular cell adhesion molecule 1 (VCAM-1)

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

ELISA

10**Description**

Plasminogen activator inhibitor-1(PAI-1)

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

ELISA

11**Description**

Tissue plasminogen activator(tPA)

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

ELISA

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

Blood Pressure

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

Digital Barometer

2**Description**

weight

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

Scale

3**Description**

Height

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

meter

4**Description**

Body mass index(BMI)

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

Computing

5

Description

Fat percent

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

Bio impedance set

6

Description

waist circumference

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

meter

7

Description

Hip circumference

Timepoint

before the intervention and 60 days after the start of the intervention

Method of measurement

meter

Intervention groups

1

Description

Intervention group: 1 capsule of 500 mg of magnesium and 2 capsules of 500 mg of placebo per day for 60 days (Nano Kimia Health Co.)

Category

Treatment - Drugs

2

Description

Intervention group: 2 capsule of 500 mg of choline and 1 capsules of 500 mg of placebo per day for 60 days (Nano Kimia Health Co.)

Category

Treatment - Drugs

3

Description

Intervention group: 2 capsules of 500 milligrams of choline and 1 capsule of 500 mg of magnesium per day for 60 days (Nano Kimia Health Co.)

Category

Treatment - Drugs

4

Description

Control group: 3 capsules of 500 mg of placebo per day for 60 days (Nano Kimia Health Co.)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Samaneh Rashvand

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Vice-Dean for research and technology Tabriz University of Medical Science

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
Dr Ali Tarighat Esfanjani
Position
associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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