

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Placebo-controlled clinical trial to determine the effects of dietary zinc supplementation on serum levels of brain-derived neurotrophic factor, vascular endothelial growth factor, advanced glycation end products, metalloproteinase 9 and caspase 3 in patients with diabetic retinopathy

Protocol summary

Study aim

The aim of this randomized, placebo-controlled trial is to investigate the effects of zinc supplementation on serum levels of brain derived neurotrophic factor(BDNF), vascular endothelial growth factor(VEGF), advanced glycation end products, Matrix Metalloproteinase 9 and caspase 3 in diabetic retinopathy patients.

Design

randomised trial with control group, parallel group, two side blinded

Settings and conduct

The participants will be assigned into control and treatment groups using permuted-blocks randomization. This reception would be for 3 months one to two hours after lunch.

Participants/Inclusion and exclusion criteria

Fifty diabetic retinopathy patients that their disease was confirmed by pathologic assessment will include in this study according inclusion (like Subject diagnosed with diabetic retinopathy) and exclusion (like Insulin injection; Having chronic diseases such as cardiovascular disorders) criteria.

Intervention groups

Treatment group will receive a 30mg zinc gluconate tablet and control group will receive a 30mg maltose-dextrin tablet.

Main outcome variables

Serum concentration of brain derived neurotrophic factor vascular endothelial growth factor, Methylglyoxal, Pentosidine, Carboxymethyl lysine, Metalloproteinase 9, Caspase 3

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040617150N1**

Registration date: **2014-08-02, 1393/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-31, 1396/11/11**

Update count: **1**

Registration date

2014-08-02, 1393/05/11

Registrant information

Name

Siamack Naghizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Placebo-controlled clinical trial to determine the effects of dietary zinc supplementation on serum levels of brain-derived neurotrophic factor, vascular endothelial growth factor, advanced glycation end products, metalloproteinases 9 and caspase 3 in patients with diabetic retinopathy

Public title

Effect of zinc supplementation in the treatment of diabetic retinopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 40-70 years old suffering from type 2 diabetes without insulin Subject diagnosed with diabetic retinopathy

Exclusion criteria:

Insulin injection Having chronic diseases such as cardiovascular disorders, renal and hepatic Having malabsorption syndrome and inflammatory bowel disease. Pregnancy and lactation Drugs interfering with zinc (Penicillin amine, Diethylenetriamine pentaacetate) ; Inhibitor drugs vascular endothelial growth factor (Avastin) Receiving nutritional supplements from 2 months before the study (zinc, calcium, vitamin A and iron) Exercise on a regular basis Having a mental illness such as depression Infectious diseases and AIDS Alcoholism

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random block method (blocks with a volume of at least 4 to prevent the blinding of the study), using RAS software

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants and the main researcher are blinded and using randomly blocked with a minimum volume of 4 to prevent the blindness of the study.

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

Golbad Street

City

Tabriz

Province

East Azarbaijan

Postal code

-

Approval date

2014-07-17, 1393/04/26

Ethics committee reference number

9359

Health conditions studied

1

Description of health condition studied

Diabetic retinopathy

ICD-10 code

H36.0

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

serum concentration of zinc

Timepoint

At baseline and after 3 months of intervention

Method of measurement

atomic absorption spectrophotometry

2

Description

serum concentration of brain derived neurotrophic factor

Timepoint

At baseline and after 3 months of intervention

Method of measurement

ELISA

3

Description

serum concentration of vascular endothelial growth factor

Timepoint

At baseline and after 3 months of intervention

Method of measurement

ELISA

4

Description

serum concentration of Methylglyoxal

Timepoint

At baseline and after 3 months of intervention

Method of measurement

ELISA

5

Description

serum concentration Pentosidine

Timepoint

At baseline and after 3 months of intervention

Method of measurement

ELISA

6

Description

serum concentration Carboxymethyl lysine

Timepoint

At baseline and after 3 months of intervention

Method of measurement

ELISA

7

Description

serum concentration Metalloproteinase 9

Timepoint

At baseline and after 3 months of intervention

Method of measurement

ELISA

8

Description

serum concentration Caspase 3

Timepoint

At baseline and after 3 months of intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

serum concentration of Insulin

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Chemiluminescence

2

Description

Fasting blood sugar

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Enzymatic colorimetric method

3

Description

serum concentration of HbA1c

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Turbidimetry

4

Description

Insulin Resistance Index

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Based on the formula of Insulin Resistance Index

5

Description

Systolic blood pressure

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Stethoscope and sphygmomanometer

6

Description

Diastolic blood pressure

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Stethoscope and sphygmomanometer

Intervention groups

1

Description

The case group will receive a 30mg zinc gluconate tablet for 3 months, one to two hours after lunch. The tablets will be provided by Jalinous pharmaceutical company in Tehran. All the patients will receive the supplements on a weekly basis and will be monitored for consumption continuation and any possible adverse effects by telephone interviews.

Category

Treatment - Drugs

2

Description

The control group will receive a 30mg maltose- dextrin tablet as placebo for 3 months, one to two hours after lunch. The tablets will be provided by the Faculty of

Pharmacy, Tabriz University of Medical Sciences. All the patients will receive the placebo on a weekly base and will be monitored for consumption continuation and any possible adverse effects by telephone interviews.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alavi Hospital

Full name of responsible person

Dr Habib Ojaghi

Street address

Maadi Street , Ardebili Avenue

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Phone**Email**

rahmatnosraty@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

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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

Vice chancellor for Research, 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

Dr. Sorayya Kheirouri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Assistant professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Siamack Naghizadeh

Position

MSc student in health sciences in nutrition

Latest degree

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Other areas of specialty/work

Nutrition

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Phone

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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable