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, metalloproteinas 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 Metalloproteinas 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 gloconate 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

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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, metalloproteinas 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 gloconate tablet for 3 months, one to two hours after lunch. The tablets will provided by jalinous pharmaceutical company in Tehran . All the patients will receive the supplements on a weekly base 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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Golbad Street
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-
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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
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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

Bachelor

Other areas of specialty/work

Nutrition

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Web page address

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