Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Placebo-controlled clinical trial to determine the effects of dietary zinc supplementation on serum levels of nerve growth factor in patients with diabetic retinopathy

Protocol summary

Summary

The aim of this randomized, placebo-controlled trial is to investigate the effects of zinc supplementation on serum levels of nerve growth factor(NGF) in diabetic retinopathy patients. Fifty diabetic retinopathy patients that their disease was confirmed by pathologic assessment will include in this study according inclusion and exclusion criteria. The participants will be assigned into control and treatment groups using permuted-blocks randomization. Treatment group will receive a 30mg zinc gloconate tablet and control group will receive a 30mg maltose-dextrin tablet for 3 month one to two hours after lunch. For determination of zinc supplementation on serum levels of NGF,this factor will measure by conventional lab method at baseline and endpoint of the study in both the groups. Finally, to manage effects of any confounder variables, anthropometric indices, physical activity level and psychological stress status will be measured and a 24-hour recall will be kept simultaneously with the measurements.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042117150N2**
Registration date: **2014-05-12, 1393/02/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-05-12, 1393/02/22

Registrant information

Name

Siamack Naghizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1661 8685

Email address

kheiroouris@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-06-15, 1393/03/25

Expected recruitment end date

2014-12-16, 1393/09/25

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 nerve growth factor in patients with diabetic retinopathy

Public title

Effect of zinc supplementation on serum levels of nerve growth factor in the treatment of diabetic retinopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age range 40-70 years old; suffering from type 2 diabetes; subject diagnosed with diabetic retinopathy based on ETDRS and the DRS criteria.

Exclusion criteria: insulin injection; hving chronic diseases such as cardiovascular disorders, renal and hepatic,asthma and allergy; having malabsorption syndrome and inflammatory bowel disease; pregnancy and lactation; drugs interfering with zinc (Penicillin amine, Diethylenetriamine pentaacetate); 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
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In the present study, Patients' awareness about their study group may act as a confounder variable on some of outcome maesures. Therefore, the study will be single-blinded and all the participants will receive tablets with identical shape, size and color.

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

Postal code

Approval date
2014-02-26, 1392/12/07

Ethics committee reference number
92206

Health conditions studied

1

Description of health condition studied
Diabetic retinopathy

ICD-10 code
H36.0*

ICD-10 code description
Diabetic retinopathy

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 nerve growth factor

Timepoint
At baseline and after 3 months of intervention

Method of measurement
ELISA

Secondary outcomes

1

Description
Insulin Resistance Index

Timepoint
At baseline and after 8 weeks of intervention

Method of measurement
HOMA-IR

2

Description
Systolic blood pressure

Timepoint
At baseline and after 8 weeks of intervention

Method of measurement
Stethoscope and sphygmomanometer

3

Description
Diastolic blood pressure

Timepoint
At baseline and after 8 weeks of intervention

Method of measurement
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

City
Ardabil

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

Street address
Golbad Street

City
Tabriz

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
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 Sciences

Full name of responsible person
Siamack Naghizadeh

Position
MSc student in health sciences in nutrition

Other areas of specialty/work

Street address
Attar Neishabouri Avenue, Golgasht Street

City
Tabriz

Postal code

Phone

Fax

Email
siamg22@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Sorayya Kheirouri

Position
Assistant professor

Other areas of specialty/work

Street address
Attar Neishabouri Avenue, Golgasht Street

City
Tabriz

Postal code

Phone
+98 41 1335 7580

Fax

Email
kheirouris@tbzmed.ac.ir

Web page address

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

Other areas of specialty/work

Street address

Attar Neishabouri Avenue, Golgasht Street

City

Tabriz

Postal code

Phone

Fax

Email

siamg22@yahoo.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