Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effect of oral supplementation of zinc on glycemic status, lipid profile and body composition in non-diabetic hemodialysis patients

Protocol summary

Study aim

Determination the effect of oral supplementation of zinc on glycemic status, lipid profile and body composition in non-diabetic hemodialysis patients

Design

In this randomized, double-blind, placebo-controlled trial, sixty-six non-diabetic hemodialysis patients were randomly divided into two groups.

Settings and conduct

The study was performed by attending the hemodialysis center of Ayatollah Taleghani Hospital and reviewing the patients' files and after providing sufficient explanations about the research design and obtaining written consent from patients with the inclusion and exclusion criteria.At first, people's general information was obtained. Subjects were coded into groups 1 and 2 by the Bias Coin method. Cans containing zinc gluconate and placebo were coded 2 and 1 by a researcher other than the researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 6 months have passed since the start of hemodialysis. Patients undergo hemodialysis 3 times a week for 4-3 hours. Non-diabetic hemodialysis patients Exclusion criteria: Patients are candidates for kidney transplant. Patients with any symptoms of gastrointestinal disorders. Patients taking penicillamine medication. Patients taking glucocorticoid medication. Patients taking estrogen medication. Patients taking the antibiotic medication. Women taking oral contraceptives. Patients taking lipid lowering medications. Patients with zinc malabsorption (Acroderma enteropathica). Pregnant and lactating women.

Intervention groups

Intervention group: Daily consumption of a 30 mg tablet of zinc gluconate for 60 days, manufactured by Dineh Iranian Pharmaceutical Company with standard therapy Control group: Daily consumption of a placebo tablet containing corn starch, made by Dineh Iranian Pharmaceutical Company with standard treatment

Main outcome variables

Glycemic status; lipid profile; body composition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191223045862N1**
Registration date: **2020-03-14, 1398/12/24**
Registration timing: **retrospective**

Last update: **2020-03-14, 1398/12/24**
Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Mohammad Mohajjel Halim

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3344 5257

Email address

mohammad.mohajjel.h@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-07, 1398/03/17

Expected recruitment end date

2019-07-08, 1398/04/17

Actual recruitment start date

2019-06-07, 1398/03/17

Actual recruitment end date

2019-07-08, 1398/04/17

Trial completion date

2019-09-15, 1398/06/24

Scientific title
The effect of oral supplementation of zinc on glycemic status, lipid profile and body composition in non-diabetic hemodialysis patients

Public title
The effect of oral supplementation of zinc on glycemic status, lipid profile and body composition in non-diabetic hemodialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
At least 6 months have passed since the start of hemodialysis. Patients undergo hemodialysis 3 times a week for 4-3 hours. Non-diabetic hemodialysis patients

Exclusion criteria:
Patients are candidates for kidney transplant. Patients with any symptoms of gastrointestinal disorders. Patients taking penicillamine medication. Patients taking glucocorticoid medication. Patients taking estrogen medication. Patients taking the antibiotic medication. Women taking oral contraceptives. Patients taking lipid lowering medications. Patients with zinc malabsorption (Acroderma enteropathica). Pregnant and lactating women.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **66**
Actual sample size reached: **61**

Randomization (investigator's opinion)
Randomized

Randomization description
At the end of the sampling, individuals were contacted to begin the intervention.At the beginning of the intervention, the patients were assigned in groups 1 and 2 respectively. The first person in group 1, the second person in group 2 continued to 66.

Blinding (investigator's opinion)
Double blinded

Blinding description
Individuals were coded into groups 1 and 2. Also Cans containing Zinc gluconate and placebo tablets were coded 2 and 1 by someone other than the researcher and provided to the researcher in order to ensure that the researcher was not informed about the type of tablet consumed by each group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Oroumia University of Medical Sciences

Street address
Oroumia University of medical science, Resalat Blvd.,Oroumia Town

City
Oroumia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2018-10-03, 1397/07/11

Ethics committee reference number
IR.UMSU.REC.1397.248

Health conditions studied

1

Description of health condition studied
non-diabetic hemodialysis patients

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Serum zinc level

Timepoint
At the beginning (day 0) and end of the intervention (day 60)

Method of measurement
Serum zinc level was measured using Dialab kit by BT-1500 autoanalyzer in micrograms / dL.

2

Description
Insulin resistance

Timepoint
At the beginning (day 0) and end of the intervention (day 60)

Method of measurement
Insulin resistance was calculated using the homeostasis model formula (HOMA-IR) as follows. HOMA-IR = [fasting

insulin (µU/L) × fasting blood glucose (mg/dl)]/405

Secondary outcomes

1

Description
Serum albumin level
Timepoint
At the beginning (day 0) and end of the intervention (day 60)
Method of measurement
Serum albumin levels were measured using Dialab kit by BT-1500 autoanalyzer and in g / dl.

2

Description
Serum insulin level
Timepoint
At the beginning (day 0) and end of the intervention (day 60)
Method of measurement
Serum insulin level were measured using Dialab ELISA kit.

3

Description
Serum glucose level
Timepoint
At the beginning (day 0) and end of the intervention (day 60)
Method of measurement
Glucose level was measured using Pars Co kit and glucose oxidase enzymatic assay.

4

Description
Total cholesterol concentration
Timepoint
At the beginning (day 0) and end of the intervention (day 60)
Method of measurement
Total cholesterol concentration was measured using Dialab kit by enzymatic photometry.

5

Description
LDL-cholesterol concentration
Timepoint
At the beginning (day 0) and end of the intervention (day 60)
Method of measurement
Dialab kit was used to measure serum LDL-cholesterol concentration.

6

Description
HDL-cholesterol concentration
Timepoint
Dialab kit was used to measure serum HDL-cholesterol concentration.
Method of measurement
At the beginning (day 0) and end of the intervention (day 60)

7

Description
Serum triglyceride concentration
Timepoint
At the beginning (day 0) and end of the intervention (day 60)
Method of measurement
Serum triglyceride concentration was measured using Dialab kit and enzymatically.

8

Description
body composition
Timepoint
At the beginning (day 0) and end of the intervention (day 60)
Method of measurement
BIA model InBody 770 was used to determine body composition indices.

Intervention groups

1

Description
Intervention group: Daily consumption of a 30 mg tablet of zinc gluconate for 60 days, manufactured by Dineh Iranian Pharmaceutical Company with standard therapy
Category
Prevention

2

Description
Control group: Daily consumption of a placebo tablet containing corn starch, made by Dineh Iranian Pharmaceutical Company with standard treatment
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Dr. Khadijeh Makhdoumi
Street address
Ayatollah Taleghani Hospital, Kashani St., Oroumia Town
City

Oroumia
Province
West Azarbaijan
Postal code
5715974677
Phone
+98 44 3348 7990
Email
hospital_taleghani@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
Street address
Oroumia University of medical science, Resalat Blvd., Oroumia Town
City
Oroumia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3193 7224
Fax
+98 44 3224 0642
Email
mohebbi_iraj@yahoo.co.uk
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Mohammad Mohajjel Halim
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Shohada dormitory, Naslow Road.,Oroumia Town
City
Oroumia
Province
West Azarbaijan
Postal code
5331678577
Phone
+98 41 3344 5257
Email
mohammad.mohajjel.h@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Mohammad Mohajjel Halim
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Shohada dormitory, Naslow Road., Oroumia Town
City
Oroumia
Province
West Azarbaijan
Postal code
5331678577
Phone
+98 41 3344 5257
Email
mohammad.mohajjel.h@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Mohammad Mohajjel Halim
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Shohada dormitory, Naslow Road., Oroumia Town
City
Oroumia
Province

West Azarbaijan

Postal code

5331678577

Phone

+98 41 3344 5257

Email

mohammad.mohajjel.h@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data file is accessible after the results are published.

When the data will become available and for how long

Start of access period 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Before starting the analysis, the results should be coordinated with the researcher for guidance.

From where data/document is obtainable

Call the following number if needed. 09145268940

What processes are involved for a request to access data/document

No special process is required.

Comments