

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effects of zinc supplementation on serum adiponectin level and insulin resistance in patients with type II diabetes mellitus

Protocol summary

Summary

This double blind randomized controlled clinical trial study was designed to investigate the effects of zinc supplementation on serum adiponectin level and insulin resistance in patients with type II diabetes mellitus compared with the control group. Total of 60 patients aged between 30 to 50 years taking antidiabetic drugs, such as Metformin or Glibenclamid, are selected from Kashan Diabetic Center, and are randomly allocated into equal groups of placebo and zinc. One group will receive 30 mg zinc gluconate daily and other receive the same tablets as placebo for 12 weeks. Diets, exercise level and medications dosage will be held constant throughout the study. After obtaining the informed consent, subjects will be assessed by dietary intake, anthropometric, clinical and medical history, and biochemical measurements at the beginning and the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811013128N1**

Registration date: **2010-11-13, 1389/08/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-11-13, 1389/08/22

Registrant information

Name

Somayyeh Asghari mahiabadi

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Endocrinology & Metabolism Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2010-03-16, 1388/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of zinc supplementation on serum adiponectin level and insulin resistance in patients with type II diabetes mellitus

Public title

The effects of zinc supplementation on serum adiponectin level and insulin resistance in patients with type II diabetes mellitus

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age between 30 to 50 years, presence of type 2 diabetes at least for one year, willingness to participate in the study and sign the informed consent, BMI=25-30, HbA1C≤8.5, Blood pressure ≤135/85 mmHg. Exclusion criteria: severe kidney, heart, liver, GI, pulmonary and infectious diseases, thyroid dysfunction, active cancer, previous myocardial infarction, recent surgery, Insulin therapy, changing in dose of medications

such as oral anti-diabetic, anti-lipidemic and anti-hypertensive drugs 3 month before and during the study, consumption of vitamin-mineral supplements 6 month before and during the study, consumption of non-steroidal anti inflammatory drugs, glucocorticoids, hormonal drugs, antidepressants, psychotropic medications, antibiotics, diuretics, three months prior to study, Following weight-reducing diet 3 months before and during the study, smoking, pregnancy, breast feeding, postmenopausal women.

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Endocrinology & Metabolism Research Center

Street address

Shariati hospital, Tehran University of Medical Sciences

City

Tehran

Postal code**Approval date**

2010-09-04, 1389/06/13

Ethics committee reference number

E-0097

Health conditions studied**1****Description of health condition studied**

diabetes mellitus type 2

ICD-10 code

E11

ICD-10 code description

Non-insulin dependent diabetes mellitus

Primary outcomes**1****Description**

plasma adiponectin

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

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

Fasting blood glucose

Timepoint

Baseline and after 12 weeks

Method of measurement

Glucose oxidase, Enzymatic colorimetric

2**Description**

Fasting insulin serum

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

3**Description**

HbA1C (Glycosilated hemoglobin)

Timepoint

Baseline and after 12 weeks

Method of measurement

Ion exchange method

4**Description**

Insulin resistance

Timepoint

Baseline and after 12 weeks

Method of measurement

HOMA-IR calculation

5**Description**

Serum triglyceride

Timepoint

Baseline and after 12 weeks

Method of measurement

Glycerol phosphate oxidase, Enzymatic colorimetric

6

Description

Total cholesterol

Timepoint

Baseline and after 12 weeks

Method of measurement

Enzymatic photometric

7

Description

HDL-cholesterol

Timepoint

Baseline and after 12 weeks

Method of measurement

Enzymatic

8

Description

LDL-cholesterol

Timepoint

Baseline and after 12 weeks

Method of measurement

Enzymatic

9

Description

hsC-Reactive Protein

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

10

Description

serum zinc

Timepoint

Baseline and after 12 weeks

Method of measurement

atomic absorption spectrophotometry

Intervention groups

1

Description

30 mg zinc (zinc gluconate) daily

Category

Treatment - Drugs

2

Description

one placebo tablet daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Diabetic Center (Golabchi Clinic)

Full name of responsible person

Somayyeh Asghari

Street address

Emam street

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology & Metabolism Research Center

Full name of responsible person

Ramin Heshmat

Street address

Shariati Hospital, Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Endocrinology & Metabolism Research Center

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

Nutrition and Biochemistry Department, School of Health, Tehran University of Medical Sciences

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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