

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 1253 0338

##### Email address

sasghari@razi.tums.ac.ir

##### 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

##### **Full name of responsible person**

Somayyeh Asghari

##### **Position**

Master Degree

##### **Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*