

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Effect of Zinc Supplementation on Insulin Resistance, Metabolic and Inflammatory Indices in non Diabetic Pregnant Women with Impaired Glucose Tolerance

#### Protocol summary

##### Summary

The aim of the current single-blind, placebo controlled randomized clinical trial is to assess the effects of zinc supplementation on insulin resistance and selected metabolic and inflammatory markers in women with impaired glucose tolerance. Total of 46 volunteer pregnant women with impaired oral glucose challenge test, between 24th to 28th weeks of gestation, will be recruited in the study. Those with history of diabetes mellitus, any active infection, chronic metabolic diseases, drug therapy, severe anemia, smoking, alcoholics and recent history of zinc supplements consumption will be excluded. All the participants will be divided into experimental and control groups using permuted blocks random sampling method and will receive 30 mg Zinc gluconate and starch for eight consecutive weeks, respectively. The blood will be drawn via venous puncture and sera will be subjected for analysis of serum glucose and insulin using an auto-analyzer. Also, tumor necrotizing factor  $\alpha$ , Leptin, adiponectin, visfatin and Zinc- $\alpha$ 2-glycoprotein will be assessed using Enzyme Linked Immunosorbant Assay. Finally, serum zinc levels will be determined by application of graphite furnace atomic absorption spectrophotometry. The data will be entered in SPSS and analyzed by appropriate pairwise comparisons statistical methods to see if there will be any effect of the intervention on the serum levels of the selected biomarkers.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201212265670N6**

Registration date: **2013-04-10, 1392/01/21**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-04-10, 1392/01/21

##### Registrant information

###### Name

Ali Tarighat-Esfajani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 914 300 5895

###### Email address

tarighata@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Deputy for Research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-04-06, 1392/01/17

##### Expected recruitment end date

2013-06-06, 1392/03/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Zinc Supplementation on Insulin Resistance, Metabolic and Inflammatory Indices in non Diabetic Pregnant Women with Impaired Glucose Tolerance

##### Public title

Effect of Zinc Supplementation on Gestational Diabetes

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criterion: 1. Pregnant women with abnormal OGTT screening test. Exclusion criteria: 1. History of Diabetes Mellitus before the current pregnancy. 2. Infection, chronic diseases, medicinal therapy, anemia. 3. History of gestational diabetes in previous pregnancy. 4. Smoking and/or alcohol consumption. 5. History of zinc supplementation.

**Age**

From **20 years** old to **40 years** old

**Gender**

Female

**Phase**

0

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

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

Single blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Tabriz University of Medical Sciences

**Street address**

Department of Nutrition, Faculty of Nutrition, Tabriz University of Medical Sciences, Ghol-Ghasht st, Tabriz, I. R. Iran

**City**

Tabriz

**Postal code**

5166614711

**Approval date**

2013-03-11, 1391/12/21

**Ethics committee reference number**

91226

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

Gestational Diabetes Mellitus

**ICD-10 code**

O24.4

**ICD-10 code description**

Diabetes mellitus arising in pregnancy

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

Serum Glucose

**Timepoint**

Before and After the Intervention

**Method of measurement**

Enzymatic

**2****Description**

Serum Insulin

**Timepoint**

Before and After the Intervention

**Method of measurement**

ELISA

**3****Description**

Insulin Resistancy

**Timepoint**

Before and After the Intervention

**Method of measurement**

HOMA-IR

**4****Description**

Serum Leptin

**Timepoint**

Before and After the Intervention

**Method of measurement**

ELISA

**5****Description**

Adiponectin

**Timepoint**

Before and After the Intervention

**Method of measurement**

ELISA

**6****Description**

Visfatin

**Timepoint**

Before and After the Intervention

**Method of measurement**

ELISA

## 7

### **Description**

Zinc- $\alpha$ 2 - Glycoprotein

### **Timepoint**

Before and After the Intervention

### **Method of measurement**

ELISA

## 8

### **Description**

TNF- $\alpha$

### **Timepoint**

Before and After the Intervention

### **Method of measurement**

ELISA

## 9

### **Description**

Fasting Blood Glucose

### **Timepoint**

Before and After the Intervention

### **Method of measurement**

Enzymatic

## 10

### **Description**

1 hour Blood Sugar

### **Timepoint**

Before and After the Intervention

### **Method of measurement**

Enzymatic

## 11

### **Description**

2 hour Blood Sugar

### **Timepoint**

Before and After the Intervention

### **Method of measurement**

Enzymatic

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention: Tab Zinc Guconate 30 mg/once a day for 2 month In intervention group 23 pregnant women after the entry qualifications will take one tablet of Zinc Guconate for 2 month and variables will be analysed before and after the intervention.

#### **Category**

Treatment - Drugs

## 2

### **Description**

Control: Placebo/once a day for 2 month/In control group 23 pregnant women after the entry qualifications will take one tablet of placebo for 2 month and variables will be analysed before and after the intervention.

### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Roh Zنده Primery Health Center 2

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

DR.Mohammad Alizadeh , MD., Ph.D.

##### **Street address**

Emam st,Shabestar

##### **City**

Shabestar

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

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

Dr. Seyed Kazem Shakouri, M. D.

##### **Street address**

Emam Reza Hospital, Golbad st, Daneshgah Ave,Tabriz, Iran

##### **City**

Tabriz

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

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**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Ali Tarighat Esfanjani

**Position**

Assistant professor

**Other areas of specialty/work****Street address**

Faculty of Nutrition, Ghol-Ghasht st, Tabriz,

**City**

Tabriz

**Postal code****Phone**

+98 41 1335 7581

**Fax****Email**

tarighata@tbzmed.ac.ir

Web page address

## Person responsible for updating data

### Contact

## 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*