Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 venus puncture and sera will be subjected for analysis of serum glucose and insulin using an auto-analyzer. Also, tumor necrotizing factor α, Leptin, adiponectin, visfatin and Zinc-α2-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-Esfanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 914 300 5895

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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-α2 - Glycoprotein
Timepoint
Before and After the Intervention
Method of measurement
ELISA

8

Description
TNF-α
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 Gluconate for 2 month and variables will be analysed before and after the intervention.
Category
Treatment - Drugs

2

Description
Control: Placebpo/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 Zendeh 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