Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Effect of zinc supplementation on insulin resistance and lipid profiles in women with gestational diabetes

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of zinc supplementation on insulin resistance and lipid profiles in gestational diabetes.

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct

Population and sample size: 58 patients with gestational diabetes mellitus among pregnant women of eligible and referred to Kosar Gynecology Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Pregnant women aged 18-40 years diagnosed with gestational diabetes mellitus at 24-28 weeks' gestation. Exclusion Criteria: Taking zinc supplements, premature preterm rupture of membrane, placenta abruption, pre-eclampsia, eclampsia, hypo- and hypothyroidism, the use of substitute treatments including hormone or vitamin supplements, complete bed rest (CBR), intra uterine fetal death (IUFD), preterm delivery.

Intervention groups

Intervention group: Zinc capsule (Donyayeh Behesht Pharmaceutical Company, Tehran, Iran), 30 mg, once a day for 6 weeks orally. Control group: Placebo capsule (Barij Essence Pharmaceutical Company, Kashan, Iran), once a day for 6 weeks orally. Patients will be assigned to receive either zinc (n=29) or placebo (n=29) for metabolic profiles, and to receive either zinc (n=20) or placebo (n=20) for gene expression.

Main outcome variables

Outcomes: Insulin and insulin resistance (primary outcomes). Fasting plasma glucose and lipid profiles, pregnancy outcomes (secondary outcome).

General information

Reason for update

Conducted date: August 2014 to April 2016. Publication date: The effect of zinc supplementation on expressed levels of peroxisome proliferator-activated receptor gamma and glucose transporter type 1 genes in newborns of women with gestational diabetes mellitus; Publication date: 22 June 2016. Zinc supplementation and the effects on pregnancy outcomes in gestational diabetes: a randomized, double-blind, placebo-controlled trial; Publication date: 14 October 2015. Zinc supplementation and the effects on metabolic status in gestational diabetes: A randomized, double-blind, placebo-controlled trial; Publication date: 4 July 2015. The number of update: 2. Reason for update: Due to an error, the request for an update in our website has conducted after paper published. However, the revisions were in accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201408295623N26**
Registration date: **2014-09-05, 1393/06/14**
Registration timing: **retrospective**

Last update: **2020-10-12, 1399/07/21**
Update count: **2**

Registration date

2014-09-05, 1393/06/14

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source
Arak University of Medical Sciences

Expected recruitment start date
2014-08-04, 1393/05/13
Expected recruitment end date
2014-08-18, 1393/05/27
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of zinc supplementation on insulin resistance and lipid profiles in women with gestational diabetes

Public title
Effect of zinc in treatment of gestational diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion Criteria: Pregnant women aged 18-40 years diagnosed with gestational diabetes mellitus at 24-28 weeks' gestation
Exclusion criteria:
Taking zinc supplements Premature preterm rupture of membrane Placenta abruption Pre-eclampsia Eclampsia Chronic hypo- and hypothyroidism The use of substitute treatments including hormone or vitamin supplements Complete bed rest (CBR) Intra uterine fetal death (IUFD) Preterm delivery
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
At study baseline after balanced blocked randomisation, participants will be allocated into two treatment groups to take either zinc supplements (n = 29) or placebo (n = 29). Randomization will be done by the use of Stat Trek software. Participants, investigators or the assessors of the outcomes are also unaware of the study groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Clinic who is not involved in the trial and not aware of random sequences will allocate the numbered bottles of capsules to participants. Supplements and placebo are in the same packaging at the pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Arak University of Medical Sciences
Street address
Vice-chancellor for Education and Research, Sardasht Avenue, Arak
City
Arak
Province
Markazi
Postal code
3814113634
Approval date
2014-08-03, 1393/05/12
Ethics committee reference number
93-165-2

Health conditions studied

1

Description of health condition studied
Gestational diabetes
ICD-10 code
O24.9
ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description
Insulin
Timepoint
At the beginning of the study and after 6 weeks of

intervention
Method of measurement
Eliza

2

Description
Insulin resistance
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Calculation with HOMA formula

3

Description
Hs-CRP
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Eliza

4

Description
Newborns PPAR-gamma
Timepoint
Cord blood of newborns of women with GDM at delivery time
Method of measurement
PCR-RT

Secondary outcomes

1

Description
Fasting blood sugar
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

2

Description
Triglycerides
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
Total cholesterol
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
HDL-cholesterol
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
VLDL-cholesterol
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
LDL-cholesterol
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Nitric oxide
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Spectrophotometry

9

Description
Glutathione
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Spectrophotometry

10

Description
Newborns' weight
Timepoint
The first 24 h after birth
Method of measurement
Scale

11

Description
Newborn length
Timepoint
The first 24 h after birth
Method of measurement
Girth measuring tape

12

Description
Newborn head circumference
Timepoint
The first 24 h after birth
Method of measurement
Girth measuring tape

13

Description
Polyhydramnios
Timepoint
After 6 weeks of intervention
Method of measurement
Sonography

14

Description
Newborns glucose transporter 1 (GLUT1)
Timepoint
Cord blood of newborns of women with GDM at delivery time
Method of measurement
PCR-RT

Intervention groups

1

Description
Intervention group: Zinc capsule (Donyayeh Behesht Pharmaceutical Company, Tehran, Iran), 30 mg, once a day for 6 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule (Barij Essence Pharmaceutical Company, Kashan, Iran), once a day for 6 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Clinic
Full name of responsible person
Maryam Karamali
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
50
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

2

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan University of Medical Sciences
Proportion provided by this source
50
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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Associate professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available