Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of the effect of zinc supplementation compared with the placebo on expressed levels of insulin receptor, PPAR-alpha and GLUT4 genes in newborns of women with gestational diabetes

Protocol summary

Study aim
Objective: The aim of this study is to determine the effects of zinc supplementation on expressed levels of insulin receptor, PPAR-alpha and GLUT4 genes in newborns of women with gestational diabetes.

Design
Parallel double-blind randomized controlled clinical trial.

Settings and conduct
50 patients with GDM among pregnant women of eligible and referred to gynecology Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation will be included in this study. Exclusion criteria will be insulin-dependent diabetes, smoking and history of kidney stones.

Intervention groups
Patients will be assigned to receive either zinc supplements (intervention group: n=25) or placebo (control group: n=25).Although the duration of intervention was 6 weeks, all women were followed up until the delivery.

Main outcome variables
Outcomes: Blood samples from cord will be taken to quantify expressed levels of insulin receptor (primary outcome), PPAR-alpha and GLUT4 genes (secondary outcomes).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201604195623N76**
Registration date: **2016-05-01, 1395/02/12**
Registration timing: **retrospective**
Last update: **2019-09-26, 1398/07/04**
Update count: **1**

Registration date
2016-05-01, 1395/02/12

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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+98 36 1534 3570

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asemi_z@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source
Kashan University of Medical Sciences

Expected recruitment start date
2016-02-20, 1394/12/01

Expected recruitment end date
2016-03-20, 1395/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of zinc supplementation compared with the placebo on expressed levels of insulin receptor, PPAR-alpha and GLUT4 genes in newborns of women with gestational diabetes

Public title

Effect of supplementation in treatment of women with gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with gestational diabetes aged 18 to 40 years

Exclusion criteria:

Insulin-dependent diabetes Smoking History of kidney stones

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: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either supplements (n = 25) or placebo (n = 25). Randomization will be done by the use of computer-generated random numbers.

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 gynecology clinics affiliated to Kashan University of Medical Sciences, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

81151-87159

Approval date

2016-03-09, 1394/12/19

Ethics committee reference number

IR.Kaums.REC.1394.163

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

Expressed levels of insulin receptor 1 gene

Timepoint

Dlivery time

Method of measurement

PCR

2

Description

Expressed levels of insulin receptor 2 gene

Timepoint

Dlivery time

Method of measurement

PCR

Secondary outcomes

1

Description

Gene expression of PPAR-alpha

Timepoint

Delivery time

Method of measurement

PCR

2

Description

Gene expression of GLUT4

Timepoint

Delivery time

Method of measurement

PCR

3

Description
Gene expression of TGFB
Timepoint
Delivery time
Method of measurement
PCR

Intervention groups

1

Description
Intervention group: Zinc supplements, 30 mg, daily, for 6 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule, daily for 6 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kashan University of Medical Sciences
Proportion provided by this source
100
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
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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