

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

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

Isfahan

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

Delivery time

Method of measurement

PCR

2

Description

Expressed levels of insulin receptor 2 gene

Timepoint

Delivery 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

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Shahid Rajaei 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

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

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Other areas of specialty/work

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Web page address**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

Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

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Latest degree

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