

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of zinc supplementation on biomarkers of inflammation, stress oxidative and pregnancy outcomes in women with gestational diabetes

Protocol summary

Study aim

The aim of this study is to determine the effects of zinc supplementation on biomarkers of inflammation and oxidative and pregnancy outcomes in gestational diabetes.

Design

Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers.

Settings and conduct

Among patients with GDM referred to Naghavi outpatient Clinic affiliated to Kashan University of Medical Sciences, 50 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 6 weeks after the intervention. At the beginning and the end of the intervention: 6 weeks.

Participants/Inclusion and exclusion criteria

Inclusion and Exclusion Criteria: Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation will be included in this study. The use of substitute treatments including hormone or vitamin supplements as well as those with preeclampsia, complete bed rest (CBR), intra uterine fetal death (IUFD), placenta abruption and preterm delivery will be excluded in the study.

Intervention groups

Patients will be assigned into two groups to receive zinc supplements (n=25) or placebo (n=25).

Main outcome variables

Outcomes: Maternal hs-CRP and newborns PPAR-gamma (primary outcomes), maternal other biomarkers of inflammation and oxidative stress outcomes (secondary outcomes) will be quantified at study baseline and end-of-trial

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201505095623N42**

Registration date: **2015-05-22, 1394/03/01**

Registration timing: **retrospective**

Last update: **2019-08-11, 1398/05/20**

Update count: **1**

Registration date

2015-05-22, 1394/03/01

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

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

2014-10-27, 1393/08/05

Expected recruitment end date

2014-11-26, 1393/09/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of zinc supplementation on biomarkers of inflammation, stress oxidative and pregnancy outcomes in women with gestational diabetes

Public title

Effect of zinc in treatment of gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation

Exclusion criteria:

The use of substitute treatments including hormone or vitamin supplements patients with preeclampsia complete bed rest (CBR) intra uterine fetal death (IUFD) placenta abruption preterm delivery

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly allocated into two groups to take either supplements or placebo. Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2014-10-25, 1393/08/03

Ethics committee reference number

3534

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

Hs-CRP

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

2

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

Total antioxidant capacity

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

2

Description

Nitric oxide

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

3

Description

Glutathione

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

4

Description

Newborns' weight

Timepoint

The first 24 h after birth

Method of measurement

Scale

5

Description

Newborn length

Timepoint

The first 24 h after birth

Method of measurement

Girth measuring tape

6

Description

Newborn head circumference

Timepoint

The first 24 h after birth

Method of measurement

Girth measuring tape

7

Description

Polyhydramnios

Timepoint

Post-intervention

Method of measurement

Sonography

8

Description

Newborns GLUT

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, 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 Rajaee Avenue, Kashan

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Sponsors / Funding sources

1

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

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
PhD of Nutrition
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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