Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The effects of combined zinc and vitamin E supplementation on pregnancy outcomes, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation in women with gestational diabetes

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of zinc and vitamin E supplementation on pregnancy outcomes, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation in patients with gestational diabetes mellitus.

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive combined vitamin E and zinc supplement (n=30) or placebo (n=30).

Settings and conduct

Among patients with gestational diabetes referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 60 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 criteria: Patients with gestational diabetes mellitus aged 18 to 40 years. Exclusion criteria: Taking any supplements before the intervention.

Intervention groups

Intervention group: 400 IU vitamin E (Zahravi, Tabriz, Iran) and 30 mg elemental zinc (Donyaye Behdasht, Tehran, Iran) daily for 6 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), daily for 6 weeks orally.

Main outcome variables

Outcomes: inflammatory factors (primary outcome) and pregnancy outcomes, oxidative stress biomarkers and gene expression related to inflammation (secondary outcomes) will be quantified at study baseline and end-of-trial..

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N57**
Registration date: **2019-04-16, 1398/01/27**
Registration timing: **retrospective**

Last update: **2019-04-16, 1398/01/27**
Update count: **0**

Registration date

2019-04-16, 1398/01/27

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-23, 1397/11/03

Expected recruitment end date

2019-02-22, 1397/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of combined zinc and vitamin E supplementation on pregnancy outcomes, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation in women with gestational diabetes

Public title

Effect of combined zinc and vitamin E supplementation in treatment of women with gestational diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Patients with gestational diabetes mellitus. Individuals aged 18 to 40 years.

Exclusion criteria:

Exclusion criteria: overt diabetes mellitus Taking any supplements before the intervention Unwillingness to cooperate.

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m2) and age (<30 and ≥30 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

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 Kosar clinic, 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 Arak University of Medical Sciences

Street address

Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences

City

Arak

Province

Isfehan

Postal code

1771844351

Approval date

2019-01-22, 1397/11/02

Ethics committee reference number

IR.ARAKMU.REC.1397.300

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

O24.9

ICD-10 code description

Unspecified diabetes mellitus in pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Hs-CRP

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Nitric oxide

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Glutathione

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

5

Description

Expressed levels of TNF gene

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

6

Description

Expressed levels of TGF-β gene

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

7

Description

Newborn's head circumference

Timepoint

Delivery time

Method of measurement

Tape

8

Description

Newborn's weight

Timepoint

Delivery time

Method of measurement

Scale

9

Description

Polyhydramnios

Timepoint

End-of-trial

Method of measurement

Sonography

10

Description

Newborn length

Timepoint

The first 24 h after birth

Method of measurement

Girth measuring tape

Intervention groups

1

Description

Intervention group: 400 IU vitamin E (Zahravi, Tabriz, Iran) and 30 mg elemental zinc (Donyaye Behdasht, Tehran, Iran) daily for 6 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran), daily for 6 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Clinic

Full name of responsible person

Mehri Jamilian

Street address

Emam Khomeyni Avenue, Arak

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8115187159

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Mohammad Arjmandzadegan
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Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences
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Arjmandzadegan.m@gmail.com
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
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
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