

# 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)

##### Phone

+98 31 5546 3378

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ostadmohammadi-vr@kaums.ac.ir

##### 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  $\geq$ 25 kg/m<sup>2</sup>) and age (<30 and  $\geq$ 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**

Isfahan

**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- $\beta$  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

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Emam Khomeyni Avenue, Arak

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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  
**Street address**  
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**  
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## Person responsible for updating data

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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