

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Clinical trial of the effect of combined magnesium and vitamin E supplementation compared with the placebo on metabolic profiles in women with gestational diabetes mellitus

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of combined magnesium and vitamin E supplementation on metabolic profiles 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 magnesium 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 aged 18 to 40 years. Exclusion criteria: Taking magnesium and vitamin E supplements 3 months before the intervention, insulin therapy required during the intervention, pre-eclampsia, eclampsia, hypo and hyperthyroidism, smokers.

##### Intervention groups

Intervention group: 250 mg magnesium (21st Century, Arizona, USA) and 400 IU vitamin E (Zahravi, Tabriz, Iran) daily for 6 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), daily for 6 weeks orally.

##### Main outcome variables

Outcomes: Markers of glycemic control (primary outcomes) and lipid profile (secondary outcomes) will be

quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170513033941N24**

Registration date: **2017-12-24, 1396/10/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-15, 1398/06/24**

Update count: **1**

##### Registration date

2017-12-24, 1396/10/03

##### Registrant information

##### Name

Mohammadreza Sharif

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5546 3378

##### Email address

ostadmohammadi-vr@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-04, 1396/09/13

##### Expected recruitment end date

2017-12-28, 1396/10/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Clinical trial of the effect of combined magnesium and vitamin E supplementation compared with the placebo on metabolic profiles in women with gestational diabetes mellitus

## Public title

Effect of combined magnesium 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 aged 18 to 40 years

### Exclusion criteria:

Exclusion criteria: Taking magnesium and vitamin E supplements 3 months before the intervention Insulin therapy required during the intervention Pre-eclampsia Eclampsia Hypo and hyperthyroidism Smokers

## 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

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

Ethics committee of Arak University of Medical Sciences

##### Street address

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

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

#### Approval date

2017-12-03, 1396/09/12

#### Ethics committee reference number

IR.ARAKMU.REC.1396.215

## 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

Insulin

#### Timepoint

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

#### Method of measurement

Elisa kit

### 2

#### Description

Insulin resistance

#### Timepoint

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

#### Method of measurement

Calculation using HOMA formula

## Secondary outcomes

### 1

#### Description

Total cholesterol

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**2**

**Description**

Triglycerides

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**3**

**Description**

HDL

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**4**

**Description**

LDL

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**5**

**Description**

FPG

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**Intervention groups**

**1**

**Description**

Intervention group: 250 mg magnesium (21st Century, Arizona, USA) and 400 IU vitamin E (Zahravi, Tabriz, 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**

Mohammad arjomandzadegan

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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**

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

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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Zatollah Asemi  
**Position**  
Nutritionist  
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## Person responsible for updating data

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## Person responsible for scientific inquiries

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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