

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Clinical trial of the effect of multi mineral-vitamin D supplementation compared with the placebo on pregnancy outcomes in women with gestational diabetes

#### Protocol summary

##### Study aim

The aim of this study is to determine the effects of multi mineral-vitamin D supplementation on pregnancy outcomes in patients of gestational diabetes.

##### Design

Study design: Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers.

##### Settings and conduct

Population and sample size: 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/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation will be included in this study. Exclusion criteria: History of placenta abruption, pre-eclampsia, eclampsia, hypo and hyperthyroidism, kidney or liver diseases, taking magnesium, zinc, calcium and vitamin D supplements prior to intervention, being smoker, insulin therapy after GDM diagnosis

##### Intervention groups

Intervention: Patients will be assigned into two groups to receive multi mineral-vitamin D (n=30) or placebo (n=30). Multi mineral-vitamin D and placebos capsules are similar in shape and size.

##### Main outcome variables

Outcomes: hs-CRP and total nitrite (primary outcomes) and biomarkers of oxidative stress and pregnancy outcomes (secondary outcome) will be quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201704225623N109**

Registration date: **2017-04-25, 1396/02/05**

Registration timing: **retrospective**

Last update: **2019-09-23, 1398/07/01**

Update count: **1**

#### Registration date

2017-04-25, 1396/02/05

#### 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

Vice chancellor for research, Arak University of Medical Sciences

#### Expected recruitment start date

2017-03-01, 1395/12/11

#### Expected recruitment end date

2017-03-19, 1395/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

## Scientific title

Clinical trial of the effect of multi mineral-vitamin D supplementation compared with the placebo on pregnancy outcomes in women with gestational diabetes

## Public title

Effect of supplementation in treatment of women with 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:

History of placenta abruption Pre-eclampsia Eclampsia Hypo and hyperthyroidism Kidney or liver diseases Taking magnesium, zinc, calcium and vitamin D supplements prior to intervention Being smoker Insulin therapy after GDM diagnosis

## 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

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

Ethics committee of Arak University of Medical Sciences

##### Street address

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

#### City

Arak

#### Province

Markazi

#### Postal code

3814113634

#### Approval date

2017-02-27, 1395/12/09

#### Ethics committee reference number

IR.ARAKMU.REC.1395.408

## Health conditions studied

### 1

#### Description of health condition studied

Gestational diabetes

#### ICD-10 code

E28.2

#### ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

## Primary outcomes

### 1

#### Description

Hs-CRP

#### Timepoint

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

#### Method of measurement

ELISA kit

### 2

#### Description

Total nitrite

#### Timepoint

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

#### Method of measurement

Spectrophotometry

## Secondary outcomes

### 1

#### Description

Total antioxidant

#### 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**

Newborn length

**Timepoint**

The first 24 h after birth

**Method of measurement**

Scale

**5****Description**

Newborns' weight

**Timepoint**

The first 24 h after birth

**Method of measurement**

Scale

**6****Description**

Polyhydramnios

**Timepoint**

After the intervention

**Method of measurement**

Sonography

**7****Description**

Newborn's head circumference

**Timepoint**

Delivery time

**Method of measurement**

Tape

**8****Description**

Newborn's bilirubin

**Timepoint**

Delivery time

**Method of measurement**

Enzymatic kit

**9****Description**

Apgar score

**Timepoint**

Delivery time

**Method of measurement**

Clinical observation

**10****Description**

Preterm delivery

**Timepoint**

After delivery

**Method of measurement**

Medical record

**11****Description**

Maternal pre-eclampsia

**Timepoint**

After delivery

**Method of measurement**

Medical record

**12****Description**

Maternal hospitalization

**Timepoint**

After delivery

**Method of measurement**

Medical record

**13****Description**

Newborns' hospitalization

**Timepoint**

After delivery

**Method of measurement**

Medical record

**Intervention groups****1****Description**

Intervention group: Multi mineral-vitamin D supplements (Vitane, Wolfratshausen, Germany), 400 mg calcium, 100 mg magnesium, 4 mg zinc, 200 IU vitamin D3, 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**

Kosar Clinic

**Full name of responsible person**

Mehri Jamilian

**Street address**

Emam Khomeyni Avenue, Arak

**City**

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Isfahan

**Postal code**

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**Phone**

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**Email**

jamilian.mehri@gmail.com

**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Arak University of Medical Sciences

**Full name of responsible person**

Mohammad Rafiee

**Street address**

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

**City**

Arak

**Province**

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**Postal code**

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**Email**

rafiee-m@auims.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, 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**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kashan University of Medical Sciences

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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