

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Effect of vitamin D supplementation on insulin resistance and inflammatory factors in women with gestational diabetes

#### Protocol summary

##### Study aim

The aim of this study is to determine the effects of vitamin D supplementation on insulin resistance, inflammatory factor and biomarkers of oxidative stress in gestational diabetes.

##### Design

Double-blind randomized controlled clinical trial

##### Settings and conduct

Among patients with gestational diabetes mellitus referred to maternity Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran, 54 patients will be selected according to inclusion and exclusion criteria.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria are including, pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks gestation. In addition, exclusion criteria are including, those with premature preterm rupture of membrane, placenta abruption, or preeclampsia; those who required commencing insulin therapy during intervention; those with hypothyroidism or urinary tract infection; those who smoked; those with kidney or liver diseases; and those taking estrogen therapy.

##### Intervention groups

Intervention group: Vitamin D supplements (Zahravi Pharm Company, Iran), 50000 IU, every 3 weeks for 6 weeks orally. Control group: Placebo supplements (Barij Essence, Kashan, Iran), every 3 weeks for 6 weeks orally

##### Main outcome variables

Serum levels of 25-hydroxyvitamin D (primary outcome), Fasting plasma glucose (FPG), serum insulin, insulin resistance, inflammatory factor and biomarkers of oxidative stress (secondary outcomes)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201305115623N7**

Registration date: **2013-05-23, 1392/03/02**

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

Last update: **2019-09-19, 1398/06/28**

Update count: **2**

##### Registration date

2013-05-23, 1392/03/02

##### 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

Kashan University of Medical Sciences

##### Expected recruitment start date

2013-05-15, 1392/02/25

##### Expected recruitment end date

2013-06-15, 1392/03/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of vitamin D supplementation on insulin resistance and inflammatory factors in women with gestational diabetes

**Public title**

Effect of vitamin D in treatment of gestational diabetes

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Pregnant women aged 18-40 years Women diagnosed with Gestational Diabetes Mellitus 24-28 weeks' gestation

**Exclusion criteria:**

Premature preterm rupture of membrane Placenta abruption Preeclampsia Those who required commencing insulin therapy during intervention Those with hypothyroidism Urinary tract infection Smoking Those with kidney or liver diseases Those taking estrogen therapy

**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: **54**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To decrease potential confounding effects, all participants will have stratified randomization according to BMI and weeks of gestation. Then, participants in each block will be randomly allocated into two treatment groups to take either vitamin D supplement or placebo. Randomization will be done by the use of Stat Trek software. Participants, investigators or the assessors of the outcomes are also unaware of the study groups. <https://stattrek.com/statistics/random-number-generator.aspx>

**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 maternity clinics affiliated with Kashan University of Medical Sciences, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules. Supplements and placebo are in the same packaging at the Barij Essence pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

**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**

81151-87159

**Approval date**

2013-05-14, 1392/02/24

**Ethics committee reference number**

P/29/5/1/605

**Health conditions studied****1****Description of health condition studied**

Gestational diabetes mellitus

**ICD-10 code**

O24.9

**ICD-10 code description**

Diabetes mellitus in pregnancy, unspecified

**Primary outcomes****1****Description**

25-hydroxyvitamin D

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

ELISA kit

**2****Description**

Newborn's lengt

**Timepoint**

Delivery time

**Method of measurement**

Tape

**Secondary outcomes**

## **1**

### **Description**

Total antioxidant capacity

### **Timepoint**

Baseline and End-of-trial

### **Method of measurement**

Spectrophotometry

## **2**

### **Description**

Glutathione

### **Timepoint**

Baseline and End-of-trial

### **Method of measurement**

Spectrophotometry

## **3**

### **Description**

High-sensitivity C-reactive protein

### **Timepoint**

Baseline and End-of-trial

### **Method of measurement**

ELISA kit

## **4**

### **Description**

Insulin

### **Timepoint**

Baseline and End-of-trial

### **Method of measurement**

ELISA kit

## **5**

### **Description**

Insulin resistance

### **Timepoint**

Baseline and End-of-trial

### **Method of measurement**

Calculation using HOMA formula

## **6**

### **Description**

Triglycerides

### **Timepoint**

Baseline and End-of-trial

### **Method of measurement**

Enzymatic kit

## **7**

### **Description**

Total cholesterol

### **Timepoint**

Baseline and End-of-trial

### **Method of measurement**

Enzymatic kit

## **8**

### **Description**

HDL

### **Timepoint**

Baseline and End-of-trial

### **Method of measurement**

Enzymatic kit

## **9**

### **Description**

Fasting plasma glucose

### **Timepoint**

Baseline and End-of-trial

### **Method of measurement**

Enzymatic kit

## **10**

### **Description**

Ponderal index

### **Timepoint**

Delivery time

### **Method of measurement**

Calculation

## **11**

### **Description**

Newborn's head circumference

### **Timepoint**

Delivery time

### **Method of measurement**

Tape

## **12**

### **Description**

Polyhydramnios

### **Timepoint**

End-of-trial

### **Method of measurement**

Sonographic

## **13**

### **Description**

Calcium

### **Timepoint**

Baseline and End-of-trial

### **Method of measurement**

Enzymatic kit

## **14**

### **Description**

Newborn's bilirubin

### **Timepoint**

Delivery time

### **Method of measurement**

Enzymatic kit

## 15

### **Description**

Apgar score

### **Timepoint**

Delivery time

### **Method of measurement**

Clinical observation

## 16

### **Description**

Newborns' hypoglycemia

### **Timepoint**

After delivery

### **Method of measurement**

Enzymatic kit

## 17

### **Description**

Preterm delivery

### **Timepoint**

After delivery

### **Method of measurement**

Medical record

## 18

### **Description**

Maternal pre-eclampsia

### **Timepoint**

After delivery

### **Method of measurement**

Medical record

## 19

### **Description**

Maternal hospitalization

### **Timepoint**

After delivery

### **Method of measurement**

Medical record

## 20

### **Description**

Newborns' hospitalization

### **Timepoint**

After delivery

### **Method of measurement**

Medical record

## 21

### **Description**

LDL cholesterol

### **Timepoint**

Baseline and End-of-trial

### **Method of measurement**

Enzymatic kit

## **Intervention groups**

### 1

#### **Description**

Intervention group: Vitamin D3 capsule ( Zahravi Pharm Co, Iran), 50000 IU, every 3 weeks for 6 weeks orally.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Placebo capsule (Barij Essence Co, Iran), every 3 weeks for 6 weeks orally.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Maternity clinics affiliated with Kashan University of Medical Sciences

##### **Full name of responsible person**

Zatollah Asemi

##### **Street address**

Ghotbe Ravandi Boulevard, Kashan

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Kashan

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beheshtihospital@kaums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kashan University of Medical Sciences

##### **Full name of responsible person**

Gholamali Hamidi

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research@kaums.ac.ir

**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**  
50  
**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

## 2

### **Sponsor**

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Mohammad Rafiei  
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Vice-chancellor for Education and Research, Sardasht Avenue, Arak  
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3848176941  
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research@arakmu.ac.ir

**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**  
50  
**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**  
Nutritionist  
**Latest degree**  
Ph.D.  
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### **Person responsible for scientific inquiries**

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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