

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Effect of calcium and vitamin D co-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 calcium and vitamin D co-supplementation on insulin resistance, inflammatory factor and biomarkers of oxidative stress in gestational diabetes.

##### Design

This study is a randomized double-blind placebo-controlled trial.

##### Settings and conduct

56 patients with GDM among pregnant women of eligible and referred to maternity clinics affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

##### Participants/Inclusion and exclusion criteria

Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation will be included in this study. Subjects with premature preterm rupture of membrane (PPROM), placenta abruption, pre-eclampsia, eclampsia, chronic hypertension, hypothyroidism, urinary tract infection, smokers and those with kidney or liver diseases or those taking estrogen therapy, those who required commencing insulin therapy during intervention and stressful life conditions will be excluded.

##### Intervention groups

Patients will be assigned to receive either calcium and vitamin D supplements (intervention group) or placebo (control group).

##### Main outcome variables

Baseline and End-of-trial fasting plasma glucose (FPG), serum insulin, insulin resistance, lipid profiles, inflammatory factors and biomarkers of oxidative stress will be measured.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201311205623N11**

Registration date: **2013-12-01, 1392/09/10**

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

Last update: **2019-09-13, 1398/06/22**

Update count: **1**

##### Registration date

2013-12-01, 1392/09/10

##### 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

2013-11-20, 1392/08/29

##### Expected recruitment end date

2014-01-19, 1392/10/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

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

**Public title**

Effect of calcium and vitamin D in treatment of 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:**

Subjects with premature preterm rupture of membrane Placenta abruption Pre-eclampsia Eclampsia Chronic hypertension Hypothyroidism Urinary tract infection Smoking Those with kidney or liver diseases Those taking estrogen therapy Stressful life conditions

**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: **56**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

At study baseline, after balance randomization, subjects will be randomly divided into two groups to take either calcium and vitamin D co-supplementation (n = 28) or placebo (n = 28). Randomization will be done by the use of computer-generated random numbers.

**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 to 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.

**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**

2013-11-20, 1392/08/29

**Ethics committee reference number**

3460/1/5/29/P

**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**

Insulin

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Elisa kit

**Secondary outcomes****1****Description**

Insulin resistance

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Calculation using HOMA formula

**2****Description**

Total cholesterol

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Enzymatic kit

**3****Description**

Triglycerides

**Timepoint**

Baseline and End-of-trial  
**Method of measurement**  
Enzymatic kit

#### 4

**Description**  
HDL  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Enzymatic kit

#### 5

**Description**  
High-sensitivity C-reactive protein  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Elisa kit

#### 6

**Description**  
Nitric oxide  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
t Spectrophotometry

#### 7

**Description**  
Glutathione  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Spectrophotometry

#### 8

**Description**  
Malondialdehyde  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Spectrophotometry

#### 9

**Description**  
Total antioxidant capacity  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Spectrophotometry

#### 10

**Description**  
Fasting blood sugar  
**Timepoint**  
Baseline and End-of-trial

**Method of measurement**  
Enzymatic kit

### **Intervention groups**

#### 1

**Description**  
Intervention group: Vitamin D3 capsule, 50000 IU, every 3 weeks for 6 weeks orally. Intervention group: Calcium tablet, 500 mg, two times a day for 6 weeks orally.  
**Category**  
Treatment - Drugs

#### 2

**Description**  
Control group: Placebo capsule, every 3 weeks for 6 weeks orally. Control group: Placebo tablet, two times a day for 6 weeks orally.  
**Category**  
Treatment - Drugs

### **Recruitment centers**

#### 1

**Recruitment center**  
**Name of recruitment center**  
Maternity clinic affiliated to Kashan University of Medical Sciences  
**Full name of responsible person**  
Zatollah Asemi  
**Street address**  
Ghotbe Ravandi Boulevard, Kashan  
**City**  
Kashan  
**Province**  
Isfahan  
**Postal code**  
81151-87159  
**Phone**  
+98 31 5546 3378  
**Email**  
asemi\_r@yahoo.com

### **Sponsors / Funding sources**

#### 1

**Sponsor**  
**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Gholamali Hamidi  
**Street address**  
Bolvare Ghotbe Ravandi, Kashan  
**City**  
Kashan  
**Province**  
Isfahan  
**Postal code**

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**Phone**

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**Email**

hamidi\_gh@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**

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**

Nutritionist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

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**Position**

Nutrition PhD

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Ph.D.

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

Nutritionist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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