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
Isfehan
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

Isfehan

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

Isfehan

Postal code

81151-87159

Phone
+98 31 5554 2999

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

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
81151-87159

Phone
+98 31 5546 3378

Email
asemi_r@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Zatollah Asemi

Position
Nutrition PhD

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Bolvare Ghotbe Ravandi, Kashan

City
Kashan

Province
Isfehan

Postal code
81151-87159

Phone
+98 36 1446 3378

Fax

Email
asemi_z@kaums.ac.ir

Web page address

Person responsible for updating data

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
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Province
Isfehan

Postal code
81151-87159

Phone
+98 31 5546 3378

Fax

Email
asemi_r@yahoo.com

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