Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Iran (Islamic Republic of)

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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
Isfehan
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
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Sponsors / Funding sources

1

Sponsor
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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
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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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
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Person responsible for updating data

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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