Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of vitamin D plus calcium co-supplementation on pregnancy outcomes in gestational diabetes

Protocol summary

Study aim
The aim of this study is to determine the effects of vitamin D plus calcium co-supplementation on pregnancy outcomes in gestational diabetes.

Design
Parallel double-blind randomized controlled clinical trial.

Settings and conduct
60 patients with GDM among pregnant women of eligible and referred to maternity Clinic affiliated to Arak University of Medical Sciences, Arak, 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. Exclusion criteria will be multiple gestation, major fetal anomalies, current illicit drug use, continuous daily Ca and/or vitamin D intake since last menstrual period, insulin-dependent diabetes, smoking and history of kidney stones.

Intervention groups
Patients will be assigned to receive either vitamin D plus calcium supplements (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables
Fasting blood samples will be taken at baseline and after 6-wk intervention to measure serum vitamin D and calcium levels. Polyhydramnios will be diagnosed with sonographic estimation method at post-intervention. Infants' weight, length, head circumference, 5-min Apgar score and ponderal index will be measured.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201407115623N23**
Registration date: **2014-07-21, 1393/04/30**
Registration timing: **retrospective**
Last update: **2019-09-15, 1398/06/24**
Update count: **1**

Registration date
2014-07-21, 1393/04/30

Registrant information

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Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source
Arak University of Medical Sciences

Expected recruitment start date
2014-02-04, 1392/11/15

Expected recruitment end date
2014-03-04, 1392/12/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of vitamin D plus calcium co-supplementation on pregnancy outcomes in gestational diabetes

Public title
Effect of supplementation 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:

Multiple gestation, Major fetal anomalies Current illicit drug use Continuous daily Ca and/or vitamin D intake since last menstrual period Insulin-dependent diabetes Smoking History of kidney stones

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and weeks of gestation, subjects will be randomly divided into two groups to take either vitamin D plus calcium supplements (n = 30) or placebo (n = 30). 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 Arak 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

Arak University of Medical Sciences

Street address

Vice-chancellor for Education and Research, Sardasht Avenue, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2014-02-03, 1392/11/14

Ethics committee reference number

92-158-19

Health conditions studied

1

Description of health condition studied

Gestational diabetes

ICD-10 code

O24.9

ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description

Newborn's weight

Timepoint

Delivery time

Method of measurement

Scale

Secondary outcomes

1

Description

Newborn's head circumference

Timepoint

Delivery time

Method of measurement

Tape

2

Description

Ponderal index

Timepoint

Delivery time

Method of measurement

Calculation

3

Description

Polyhydramnios

Timepoint

End-of-trial

Method of measurement

Sonographic

4

Description
Newborn's length
Timepoint
Delivery time
Method of measurement
Tape

5

Description
Newborn's bilirubin
Timepoint
Delivery time
Method of measurement
Enzymatic kit

6

Description
Apgar score
Timepoint
Delivery time
Method of measurement
Clinical observation

7

Description
Newborns' hypoglycemia
Timepoint
After delivery
Method of measurement
Enzymatic kit

8

Description
Preterm delivery
Timepoint
After delivery
Method of measurement
Medical record

9

Description
Maternal pre-eclampsia
Timepoint
After delivery
Method of measurement
Medical record

10

Description
Maternal hospitalization
Timepoint
After delivery
Method of measurement
Medical record

11

Description
Newborns' hospitalization
Timepoint
After delivery
Method of measurement
Medical record

Intervention groups

1

Description
Intervention group: Vitamin D3 capsule, 50000 IU, every 3 weeks for 6 weeks orally.
Category
Treatment - Drugs

2

Description
Intervention group: Calcium tablet, 500 mg, two times a day for 6 weeks orally.
Category
Treatment - Drugs

3

Description
Control group: Placebo capsule, every 3 weeks for 6 weeks orally.
Category
Treatment - Drugs

4

Description
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 clinics affiliated to Arak University of Medical Sciences
Full name of responsible person
Maryam Karamali
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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
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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