

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 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

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

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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Imam street, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

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

Full name of responsible person
Zatollah Asemi

Position
Nutritionist

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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