Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Different Doses of Vitamin D Supplementation on Pregnancy Outcomes in Gestational Diabetes women

Protocol summary

Summary

Objectives: Comparison of Effects Different Doses of Vitamin D Supplementation on Pregnancy Outcomes in Gestational Diabetes women. Design: Randomized, single-blind, Ḍouble-center, phase II trial. Setting and conduct: For Group A, two times the baseline and day 21 of the study, vitamin IU D3 400 is administered.For Group B, two times the baseline and day 21 of the study, vitamin IU D3 50000 is administered.For Group Control, two times the baseline and day 21 of the study, placebo is administered. 10 days after delivery, outcomes pregnancy of patient is evaluated. Participants including major eligibility criteria: Inclusion criteria include: Pregnant women with gestational diabetes who have inadequate levels of vitamin D; exclusion criteria include: Irregular consumption of prescribed supplements. Intervention: For Group A, two times the baseline and day 21 of the study, vitamin IU D3 400 is administered.For Group B, two times the baseline and day 21 of the study, vitamin IU D3 50000 is administered.For Group Control, two times the baseline and day 21 of the study, placebo is administered. Main outcome measures variable: outcomes pregnancy after taking the supplements.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604067520N2**
Registration date: **2016-08-30, 1395/06/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-30, 1395/06/09

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Different Doses of Vitamin D Supplementation on Pregnancy Outcomes in Gestational Diabetes women

Public title

Effects of Vitamin D Supplementation on Gestational Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Participants including major eligibility criteria: Inclusion criteria include: Pregnant women with gestational diabetes who have inadequate levels of vitamin D;

exclusion criteria include: Irregular consumption of prescribed supplements.

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **192**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences

Street address
Building No 2, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

City
Kermanshah

Postal code

Approval date
2015-10-20, 1394/07/28

Ethics committee reference number
KUMS.REC.1394.261

Health conditions studied

1

Description of health condition studied
Consequences of postpartum

ICD-10 code
Z39

ICD-10 code description
Postpartum care and examination

Primary outcomes

1

Description
Birth weight

Timepoint
10 days after delivery

Method of measurement
By gram and a digital balance

2

Description
Birth height

Timepoint
10 days after delivery

Method of measurement
By cm and a centimeter standard

3

Description
Birth round head

Timepoint
10 days after delivery

Method of measurement
By cm and a centimeter standard

4

Description
Macrosomia

Timepoint
10 days after delivery

Method of measurement
By birth weight

5

Description
Apgar score at 1 and 5 minutes

Timepoint
10 days after delivery

Method of measurement
By apgar score

6

Description
Hypoglycemia

Timepoint
10 days after delivery

Method of measurement
By laboratory results

Secondary outcomes

empty

Intervention groups

1

Description
Vitamin IU D3 400, Baseline and day 21 of the study.

Category
Treatment - Drugs

2

Description
Vitamin IU D3 50000, Baseline and day 21 of the study.
Category
Treatment - Drugs

3

Description
Placebo, Baseline and day 21 of the study.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr Farahnaz Keshavarzi
Street address
Department of obstetrics and gynecology, Imam Reza Hospital, Sorkhalizheh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Dr Behrozeh Hamzeh
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Building No 2, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd
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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
Vice chancellor for research, Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Kermanshah University of Medical sciences
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Specialist in obstetrics and gynecology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty