

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 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, Double-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

Name

Farahnaz Keshavarzi

Name of organization / entity

Kermanshah University of Medical Sciences (KUMS)

Country

Iran (Islamic Republic of)

Phone

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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

City

Kermanshah

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

Full name of responsible person

farahnaz Keshavarzi

Position

Specialist in obstetrics and gynecology

Other areas of specialty/work**Street address**

Department of obstetrics and gynecology, Imam Reza Hospital, Sorkhalizheh.

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

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Position

Obstetrics and gynecology specialist

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

Farzaneh Azizi

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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jhoseini2003@gmail.com

Web page address**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