

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A clinical trial to investigate the effect of vitamin D supplementation on glucose status in mothers with gestational diabetes

Protocol summary

Summary

The main objective of this study is determining the effect of vitamin D supplementation on glucose status in mothers with gestational diabetes. This investigation is a randomized controlled clinical trial on 40 pregnant women with gestational diabetes in first trimester who are admitted in gynecology clinic in Kerman. Inclusion criteria: women over 18 year-old and gestational age of 18 to 13 week. Exclusion criteria: kidney or hepatic failure; alcoholism; malabsorption; hypo or hyperparathyroidism; malignancies; consumption of drugs affecting vitamin D metabolism; using vitamin D supplements; history of diabetes. Glucose Tolerance Test (GTT) is done by injecting 75 gr Glucose and patients with abnormal results are divided into two groups using simple randomization. Both groups will have nutritional regimen. Beside this regimen, in intervention group oral vitamin D (50000 IU) is given every two weeks for three doses and control group does not receive any supplemental vitamin D. During this period, patients who need insulin will be excluded. Two weeks following the last dose of vitamin D, FBS, fasting insulin and HbA1c level will be measured and HOMA-IR is calculated. Also the patients will be observed for gestational problems including intrauterine fetal death (IUFD), Intrauterine growth restriction (IUGR), Large for gestational age (LGA), preeclampsia, premature birth, abortion and requirement for insulin regimen until the end of pregnancy. After labour, a sample of umbilical cord is taken for measuring vitamin D level and the association of it with gestational problems will be determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122725725N1**

Registration date: **2016-01-08, 1394/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-08, 1394/10/18

Registrant information

Name

Tayebeh Naderi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3322 2250

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t_naderi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to investigate the effect of vitamin D supplementation on glucose status in mothers with gestational diabetes

Public title

Effect of vitamin D supplementation on controlling blood sugar in patients with gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women over 18 year-old; gestational age of 18 to 13 week. Exclusion criteria: kidney or hepatic failure; alcoholism; malabsorption; hypo or hyperparathyroidism; malignancies; consumption of drugs affecting vitamin D metabolism; using vitamin D supplements; history of diabetes.

Age

From **17 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Kerman University of Medical sciences

Street address

Shafa Square

City

Kerman

Postal code

Approval date

2015-10-27, 1394/08/05

Ethics committee reference number

IR.KMU.REC.1394.203

Health conditions studied

1

Description of health condition studied

Gestational diabetes

ICD-10 code

O24

ICD-10 code description

Diabetes mellitus in pregnancy

Primary outcomes

1

Description

HbA1c level

Timepoint

two weeks after the last dose of Vitamin D

Method of measurement

BLOOD TEST

2

Description

FBS (fasting blood sugar)

Timepoint

two weeks after the last dose of Vitamin D

Method of measurement

BLOOD TEST

3

Description

INSULIN LEVEL IN BLOOD

Timepoint

two weeks after the last dose of Vitamin D

Method of measurement

BLOOD TEST

4

Description

Insulin resistance

Timepoint

two weeks after the last dose of Vitamin D

Method of measurement

Homeostasis model assessment (HOMA-IR)

Secondary outcomes

1

Description

IUFD (intrauterine fetal death)

Timepoint

during pregnancy

Method of measurement

sonography

2

Description

IUGR (Intrauterine growth restriction)

Timepoint

during pregnancy

Method of measurement

sonography

3

Description

LGA (Large for gestational age)

Timepoint

during pregnancy

Method of measurement

sonography

4

Description

preeclampsia

Timepoint

during pregnancy

Method of measurement

Examination

5

Description

premature birth

Timepoint

during pregnancy

Method of measurement

Examination

6

Description

vitamin D level of umbilical cord

Timepoint

after birth

Method of measurement

Diazon kit

Intervention groups

1

Description

In intervention group: oral vitamin D (50000 IU) every two weeks is given for three doses

Category

Treatment - Drugs

2

Description

control group: they do not receive any supplemental vitamin D

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Afzalipoor Hospital

Full name of responsible person

Sonia Ahmadi

Street address

Afzalipoor Hospital, Zendan Square

City

Kerman

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Hassani

Street address

Tahmasbabad Square, Ebnesina Street

City

Kerman

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, Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

TAYEBEH NADERI

Position

gynecologist

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

Afzalipoor Hospital, Zendan Square

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KERMAN

Postal code**Phone**

+998 3432235011

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t_NADERI@KMU.AC.IR

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mohadess Peydayesh

Position

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mohades.peydayesh@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mohadess Peydayesh

Position

Assistant of gynecology

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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