Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity
Kerman University of Medical Sciences
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Iran (Islamic Republic of)
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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
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gynecologist
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Person responsible for scientific inquiries

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Name of organization / entity
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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