Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study of the effect of vitamin D oral supplementation on glycemic control, serum levels of growth hormone, insulin-like growth factor-1 and lipid profile in gestational diabetes mellitus patients

Protocol summary

Study aim

The purpose of this study is to determine the effect of Vitamin D oral supplementation on glycemic control, serum levels of Growth Hormone, Insulin-Like Growth Factor-1 and Lipid Profile in Gestational Diabetes Mellitus patients

Design

This is a randomized, double-blind, placebo-controlled clinical trial. The final sample includes 30 gestational diabetes patients who have been selected by convenience sampling method and will be placed randomly in two groups of intervention (n=15) and control (n=15). This study will be done within 6 weeks.

Settings and conduct

At the baseline and the end of study, blood samples will be collected and the growth hormone, Insulin-like growth factor-1, lipid profile and glycemic status in patients will be compared before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: detection of Gestational Diabetes Between 24-28 weeks of pregnancy, tend to participate in the study, age category between 18-40 years old, consumption of daily multivitamins; Exclusion criteria: twin or multiple pregnancy, having a Body Mass Index greater than 40, consumption of Vitamin D supplementation at least three months before the intervention, consumption of Insulin or Metformin, people with cardiovascular diseases, digestive disorders, hypertension, inflammatory diseases and hypothyroidism due to the effect on insulin metabolism and lipid profile.

Intervention groups

The intervention group will receive one tab containing 2000 IU vitamin D3 daily for 6 weeks; The control group will receive one plasebo containing paraffin oil daily for 6 weeks.

Main outcome variables

Vitamin D, growth hormone, insulin like growth factor-1, glucose, insulin, Cholesterol, triglyceride

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130616013678N29**
Registration date: **2019-03-26, 1398/01/06**
Registration timing: **retrospective**

Last update: **2019-03-26, 1398/01/06**
Update count: **0**

Registration date

2019-03-26, 1398/01/06

Registrant information

Name
Saeed Ghavamzadeh
Name of organization / entity
Urmia University of Medical Sciences
Country
Iran (Islamic Republic of)
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ghavamzadeh_s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-11, 1397/05/20

Expected recruitment end date

2019-01-10, 1397/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of vitamin D oral supplementation on glycemic control, serum levels of growth hormone, insulin-like growth factor-1 and lipid profile in gestational diabetes mellitus patients

Public title

Effect of vitamin D supplementation on control of gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Detection of gestational diabetes between 24-28 weeks of pregnancy Tend to participate in the study Age category between 18-40 years old Consumption of daily multivitamins

Exclusion criteria:

Twin or multiple pregnancy Having a body mass index greater than 40 Consumption of Vitamin D supplementation at least three months before the intervention Consumption of Insulin or Metformin People with cardiovascular diseases, digestive disorders, hypertension, inflammatory diseases and hypothyroidism Using cigarette and alcohol due to the effect on insulin metabolism and lipid profile

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Words of "intervention" and "control" will be writen on the 30 sheets and will be placed in Sealed envelope. Each patient will be asked to pick a envelope randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blinded clinical trial that participants are randomly classified into two groups of intervention and control and none of them know in which group they are. Researchers are unaware which participants are receiving the real treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Orjhans street, Resalat Blvd, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-05-30, 1397/03/09

Ethics committee reference number

IR.UMSU.REC.1397.100

Health conditions studied

1

Description of health condition studied

Gestational Diabetes Mellitus

ICD-10 code

O24

ICD-10 code description

Diabetes Mellitus in pregnancy

Primary outcomes

1

Description

25 Hydroxy Vitamin D3

Timepoint

Before and 6 weeks after trials

Method of measurement

ElectroChemi Luminescence method

2

Description

Fasting Blood Sugar

Timepoint

Before and 6 weeks after trials

Method of measurement

Enzymatic method

3

Description

Serum Insulin

Timepoint
Before and 6 weeks after trials
Method of measurement
ELISA method

4

Description
Total Cholesterol
Timepoint
Before and 6 weeks after trials
Method of measurement
Enzymatic method

5

Description
Triglyceride
Timepoint
Before and 6 weeks after trials
Method of measurement
Enzymatic method

6

Description
LDL Cholesterol
Timepoint
Before and 6 weeks after trials
Method of measurement
Enzymatic method

7

Description
HDL Cholesterol
Timepoint
Before and 6 weeks after trials
Method of measurement
Enzymatic method

8

Description
Growth Hormone
Timepoint
Before and 6 weeks after trials
Method of measurement
ELISA method

9

Description
Insulin Like Growth Factor-1
Timepoint
Before and 6 weeks after trials
Method of measurement
ELISA method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The Intervention group will receive a Vitamin D3 2000 IU supplement daily for the period of 6 weeks.
Category
Treatment - Other

2

Description
Control group: The control group will receive a placebo that is similar to Vitamin D supplements but contains Paraffin oil daily for the period of 6 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Midwifery clinic of Shahid Motahhari Hospital
Full name of responsible person
Fatemeh Mohammadi
Street address
Midwifery clinic of Shahid Motahhari Hospital, Ayatollah Kashani street, Urmia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr Iraj Mohebbi
Street address
Urmia University of Medical Sciences staffs department, Orjhans Street, Resalat Blvd, Urmia, Iran
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Email

mohebbi_iraj@yahoo.co.uk

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr Saeid Ghavamzadeh

Position

PhD in Nutrition Science and associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Nutrition Department, Faculty of Medicine, Urmia University of Medical Science, 11th Km of Nazloo Road, Urmia

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr Saeid Ghavamz

Position

دکترای علوم تغذیه و دانشیار

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Fatemeh Mohammadi

Position

Masters student

Latest degree

Bachelor

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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available