Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 2026

Comparison of the effect of vitamin D supplementation on fasting plasma glucose and insulin resistance indices in pregnant women with gestational diabetes mellitus with a group of gestational diabetic pregnant women who do not receive vitamin D supplement

Protocol summary

Study aim

The aim of study is to determine the effect of vitamin D supplementation on declining insulin resistance and improving blood glucose control in pregnant women with gestational diabetes.

Design

This study is based on parallel triple blind randomized control trial.Randomization was done by block randomization method.The sample size is 44 in total.The trial is in Phase 3

Settings and conduct

The duration of intervention will be 6 weeks for each participant. Participants and investigators will be blind. Intervention group will receive 50,000 IU of oral vitamin D supplement twice (at baseline and at 21 days after intervention) in combination with oral calcium carbonate 1000 mg/ daily .The control group will receive placebo twice at baseline and at 21 days after intervention) with oral calcium carbonate 1000 mg tablet daily.The site of this study is the Endocrine Clinic of Hormozgan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 18 to 40 After first trimester of pregnancy GDM diagnosis based on standard diagnostic test and confirmation of a obstetrician Tendency to attend the study. Exclusion criteria: Preeclampsia, insulin therapy, hypothyroidism, urinary infection diseases, smoking, renal and liver diseases

Intervention groups

Subjects in intervention groups will receive 50000 IU vitamin D3 supplement twice during the study (at baseline and at 21 days) along with 1000 mg/daily calcium carbonate supplement, and those in the placebo group Will receive 2 placebos at the same times and 1000 mg/daily calcium carbonate supplement.

Main outcome variables

Fasting plasma glucose, serum lipid profile (Triglyceride, Cholesterol, Low-density lipoprotein, High-density lipoprotein), blood level of vitamin D, plasma insulin level, blood calcium and phosphorus level, and insulin resistance will be assayed via calculating HOMA-IR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150607022585N3**
Registration date: **2018-09-22, 1397/06/31**
Registration timing: **retrospective**

Last update: **2018-09-22, 1397/06/31**
Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Masoumeh Kheirandish

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date
2015-11-04, 1394/08/13
Expected recruitment end date
2016-08-18, 1395/05/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of vitamin D supplementation on fasting plasma glucose and insulin resistance indices in pregnant women with gestational diabetes mellitus with a group of gestational diabetic pregnant women who do not receive vitamin D supplement

Public title
Effect of vitamin D supplementation on fasting plasma glucose and insulin resistance indices in gestational diabetes mellitus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women diagnosed with gestational diabetes at the age of 18-40 years. Pregnant women diagnosed with gestational diabetes who had not a previous history of overt diabetes. Pregnant women diagnosed with gestational diabetes who do not receive vitamin D supplement. Pregnant women diagnosed with gestational diabetes who do not smoke or do not use any drugs Pregnant women with gestational diabetes who do not have any systemic diseases including liver disease, hypertension, hypothyroidism. Pregnant women diagnosed with gestational diabetes who do not have multiple pregnancies Pregnant women diagnosed with gestational diabetes who do not take any medication which affect glucose metabolism like steroids and insulin Pregnant women diagnosed with gestational diabetes who do not take and medication any glucose lowering drugs.
Exclusion criteria:
unwillingness of participants to continue the study Start of insulin therapy during intervention miscarriage
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was done using software and block randomization method. The participants were divided into two groups: intervention and control.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Blinding was carried out at the participant level, researchers, expert in the field and analysing the data
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethices Committee of Hormozgan University of Medical Sciences
Street address
Chamran Blvd. Hormozgan University of Medical Sciences
City
Bandar-Abbas
Province
Hormozgan
Postal code
7916613885
Approval date
2015-07-20, 1394/04/29
Ethics committee reference number
hums.REC.1394.026

Health conditions studied

1

Description of health condition studied
Gestational Diabetes Mellitus
ICD-10 code
E10-E14
ICD-10 code description
Diabetes Mellitus

Primary outcomes

1

Description
Fasting Plasma Glucose
Timepoint
at baseline of study- at the end of 6 weeks intervention

Method of measurement
commercial kit, enzymatic method

2

Description
انسولین سرم
Timepoint
at baseline of study- at the end of 6 weeks intervention
Method of measurement
immunoassay (Elisa) kit

3

Description
Insulin resistance index (HOMA-IR)
Timepoint
at baseline of study- at the end of 6 weeks intervention
Method of measurement
using formula

Secondary outcomes

1

Description
serum triglyceride
Timepoint
at study baseline and at the end of 6 weeks intervention
Method of measurement
enzymatic method by using commercial kit

2

Description
serum total cholesterol
Timepoint
at study baseline and at the end of 6 weeks intervention
Method of measurement
enzymatic method by using commercial kit

3

Description
LDL-C
Timepoint
at study baseline and at the end of 6 weeks intervention
Method of measurement
enzymatic method by using commercial kit

4

Description
HDL-C
Timepoint
at study baseline and at the end of 6 weeks intervention
Method of measurement
enzymatic method by using commercial kit

5

Description
Serum vitamin D concentration
Timepoint
at study baseline and at the end of 6 weeks intervention
Method of measurement
Commercial kit

6

Description
serum calcium
Timepoint
at study baseline and at the end of 6 weeks intervention
Method of measurement
Commercial kit

7

Description
Serum phosphorus
Timepoint
at study baseline and at the end of 6 weeks intervention
Method of measurement
Commercial kit

Intervention groups

1

Description
The control group received placebo twice (baseline and 21 days) in combination with calcium carbonate tablets 1000 milligram orally daily
Category
Placebo

2

Description
intervention group recieved 50,000 IU of oral vitamin D twice (baseline and 21 days) in combination with oral calcium carbonate 1000 milligram tablet daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Hormozgan University of Medical Science
Full name of responsible person
Kimia Seddighi
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SHARIATI street, SEYYED JAMAL AD-DIN ASADABADI BLVD
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Nejatizadeh Abdolazim

Street address

Vice Chancellor for Research, Shahid Mohammadi Hospital, Jomhori Blvd.

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Province

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mail@hums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

kimia Seddighi

Position

Internal Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Masoumeh Kheirandish

Position

Endocrinologist

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

Endocrinologist

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

The main Outcomes will be shared after deidentified participants

When the data will become available and for how long

Data will become available after publication of the whole results of the study for one year

To whom data/document is available

Data will be accessible for researcher in universities, research centers and academic institutions

Under which criteria data/document could be used

The principal investigator of the trial, if other researchers need to more statistic analysis, after receiving the explicit request by electronic mail, will send the results of additional analysis to researchers through electronic mail.

From where data/document is obtainable

To receive documents contact with principal investigator through electronic mail. The main researcher: Dr masoumeh Kheirandish, Endocrinologist, Endocrine and Metabolism Research Center, Hormozgan University of Medical Sciences 1) Electronic Mail: Kheirandishm@yahoo.com masoumeh.kheirandish@hums.ac.ir 2) After publication of study, the results, study protocol, and more documents will be accessible in http://eprints.hums.ac.ir

What processes are involved for a request to access data/document

After Receiving the request through electronic mail, the principal investigator will immediately response to applicant, and based on the type of requested document, the exact time of sending the documents will be explain.

Comments