Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

The Effect of Vitamin D on Insulin Resistance Biomarker and Fasting Blood Glucose in Pregnant Women: A Randomized Controlled Trial.

Protocol summary

Study aim
To determine the effect of vitamin D on insulin resistance index and fasting blood glucose in pregnant women

Design
A concealed, randomized, triple blind, controlled clinical trial with a parallel group design of 88 women, phase 3.

Settings and conduct
Sampling will be done in densely populated and socio-economically different centers of Malayer. Participants in the study will be assigned to two groups by stratified block randomization method (stratification based on deficient or insufficient serum levels of vitamin D) with block sizes of 4 and 6 and a allocation ratio of 1: 1 and using the website www.random.org . The allocation sequence will be identified by a person not involved in the study using a randomizer, and the 4,000-unit drug and placebo will be placed in the same packages numbered sequentially.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women with gestational age of 8-10 weeks and vitamin D levels below 30 ng/ml
Exclusion criteria: Women with diabetes, thyroid and parathyroid disorders, history of macrosom neonate, body mass index above 30 kg/m2 before pregnancy, pre-pregnancy polycystic ovary syndrome and history of diabetes or gestational diabetes will be excluded from the study.

Intervention groups
The intervention group will receive 4 oral tablets of vitamin D 1000 units daily and the control group will receive placebo which is quite similar in appearance to the drug used in the intervention group.

Main outcome variables
Insulin Resistance Index Serum level of fasting blood glucose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N59**
Registration date: **2020-11-04, 1399/08/14**
Registration timing: **prospective**

Last update: **2020-11-04, 1399/08/14**
Update count: **0**

Registration date
2020-11-04, 1399/08/14

Registrant information

Name
Mojgan Mirghafourvand

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 41 1479 6969

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-04-20, 1400/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Vitamin D on Insulin Resistance Biomarker and Fasting Blood Glucose in Pregnant Women: A

Randomized Controlled Trial.

Public title
The effect of Vitamin D on fasting plasma glucose and Insulin levels
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women with gestational age of 8 -10 weeks Vitamin D levels below 30 ng / ml
Exclusion criteria:
Women with diabetes Vitamin D levels above 30 ng / ml Women with thyroid and parathyroid disorders according to the self-report Women with a history of macrosomic neonate Women with a body mass index above 30 kg / m2 before pregnancy Women with pre-pregnancy polycystic ovary syndrome, according to the self-report Women with a history of diabetes or gestational diabetes
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants in the study will be assigned to two groups (one group receiving 4,000 units of oral vitamin D daily and one group receiving placebo with the same protocol) by stratified block randomization method (stratification based on deficient or insufficient serum levels of vitamin D) with block sizes of 4 and 6 and a allocation ratio of 1: 1 and using the website www.random.org . To hide the Allocation (Allocation Concealment), the allocation sequence will be identified by a person not involved in the study using a randomizer, and the 4,000-unit drug and placebo will be placed in the same packages numbered sequentially.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The participants, researcher and data analyst will be blinded completely in this study. Drug and placebo will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person not involved in the research.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2020-11-01, 1399/08/11
Ethics committee reference number
IR.TBZMED.REC.1399.759

Health conditions studied

1

Description of health condition studied
Gestational Diabetes
ICD-10 code
O24.4
ICD-10 code description
Gestational diabetes mellitus

Primary outcomes

1

Description
Insulin resistance index
Timepoint
Before the intervention - 26 weeks of pregnancy
Method of measurement
HOMA-IR index

2

Description
Fasting plasma glucose levels
Timepoint
Before the intervention - 26 weeks of pregnancy
Method of measurement
FBS

3

Description

Fasting plasma insulin levels

Timepoint

Before the intervention - 26 weeks of pregnancy

Method of measurement

FBI

Secondary outcomes

1

Description

Abortion rate

Timepoint

26 weeks of pregnancy

Method of measurement

Abortion checklist

2

Description

Gestational Diabetes

Timepoint

26 weeks of pregnancy

Method of measurement

OGTT - FBS

3

Description

Depression score

Timepoint

26 weeks of pregnancy

Method of measurement

Edinburgh Depression Questionnaire

4

Description

Side effects

Timepoint

26 weeks of pregnancy

Method of measurement

Side effects checklist

Intervention groups

1

Description

The intervention group will receive 4000 units of oral vitamin D daily produced by Dana Pharmaceutical Company, which is quite similar in appearance to the drug used in the placebo group. This intervention will last for 17 weeks.

Category

Treatment - Drugs

2

Description

The control group will receive an oral placebo daily produced by Dana Pharmaceutical Company, which in terms of appearance is quite similar to the drug used in the intervention group. This study will last for 17 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Malayer city

Full name of responsible person

Zahra Mirzaee Azandaryani

Street address

Malayer city

City

Malayer

Province

Hamadan

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6578146769

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Mirzaee Azandaryani

Position

MSc student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Mirghafourvand

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Associate Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participant data is confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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 results of the clinical trial will be published in the form of an article.

When the data will become available and for how long

Immediately after the publication of the results.

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific use with reference to the article

From where data/document is obtainable

mirghafourvandm@tbzmed.ac.ir

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

Up to one week after correspondence by email

Comments