

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Effect of different doses of vitamin D on insulin resistance in pregnant women attending in Shahid Sadoughi and Mojobian prenatal clinics

Protocol summary

Summary

The objective of this randomized, not blinded trial is to investigate the effect of different doses of vit D on the insulin resistance in pregnant women. In this study, 90 pregnant women who meet the inclusion/exclusion criteria will be recruited and randomly assigned into two interventions or control group. The pregnant women in the intervention groups will receive 2000 or 4000 IU vit D daily for 6 months while in the control group will receive 200 IU (conventional dose) vit D, daily for 6 months. Fasting blood sugar, 25 hydroxy vit D, insulin and homeostatic model assessment (HOMA) will be measured before and after the intervention and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811203312N1**
Registration date: **2011-05-23, 1390/03/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-05-23, 1390/03/02

Registrant information

Name

Sedigheh Soheilykhah

Name of organization / entity

Yazd Diabetes Research Center, Shahid Sadoughi
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1522 3999

Email address

s_soheilykhah@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd Diabetes Research Center, Shahid Sadoughi
University of Medical Sciences

Expected recruitment start date

2010-03-06, 1388/12/15

Expected recruitment end date

2011-09-06, 1390/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of different doses of vitamin D on insulin resistance in pregnant women attending in Shahid Sadoughi and Mojobian prenatal clinics

Public title

Effect of different doses of vitamin D on insulin resistance in pregnant women attending in Shahid Sadoughi and Mojobian prenatal clinics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women with gestational age less than 12 weeks without gestational diabetes, history of PCO, BMI less than 27kg/m² before pregnancy, no Vit D supplementation in the past 6 months
Exclusion criteria: diabetes or gestational diabetes treated with insulin, thyroid or parathyroid disorders, hypertension, polycystic ovary (PCO) s

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

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

Yazd Diabetes Research Center, Shahid Sadoughi
University of Medical Sciences

Street address

Afshar Alley, Jomhuri BLV. , Yazd, Iran

City

Yazd

Postal code

8917965556

Approval date

2010-08-08, 1389/05/17

Ethics committee reference number

48204/17/پ

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

Insulin

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Insulin kit

2

Description

Vitamin D

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Vit D kit

3

Description

FBS

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Auto Analyser method

4

Description

Insulin resistance Index

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Measuring of HOMA index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Vit D supplementation, 2000 IU,
daily for 6 months

Category

Treatment - Drugs

2

Description

Control group: vit D, 200 IU (conventional dose), daily for
6 months

Category

Treatment - Drugs

3

Description

Intervention group2: Vit D supplementation, 4000 IU,
daily for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi and Mojibian prenatal clinics in Yazd

Full name of responsible person

Dr. Sedigheh Soheilykhah

Street address

Shahid Sadoughi hospital, Yazd, Iran

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Diabetes Research Center, Shahid Sadoughi
University of Medical Sciences

Full name of responsible person

Dr. Sedigheh Soheilykhah

Street address

Afshar Alley, Jomhuri BLV. , Yazd, Iran

City

Yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yazd Diabetes Research Center, Shahid Sadoughi
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

Yazd Diabetes Research Center, Shahid Sadoughi
University of Medical Sciences

Full name of responsible person

Dr. Sedigheh Soheilykhah

Position

Assistant professor of internal medicine

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

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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