

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of vitamin D supplementation on glucose status, lipid profiles and inflammatory factors in mothers with a history of gestational diabetes

Protocol summary

Summary

This investigation is a randomized controlled clinical trial to determine the effect of vitamin D supplementation on glucose status, lipid profiles and inflammatory factors in mothers with a history of gestational diabetes. The sample size of study is 44 cases. They are randomly selected according to age and BMI from the list of Yazd Diabetes Research Center. After review of inclusion criteria and obtaining consent, they are assigned to two groups based on random numbers table. Then, up to 10 days after delivery, they are invited to visit Yazd Diabetes Research Center. Women in active arm receive intramuscular injection of vitamin D with 300,000 international units dose and the control group does not receive any complementary. Glucose, insulin, triglyceride, LDL and HDL cholesterol and 25-hydroxy vitamin D and also inflammatory factor that is effective in causing diabetes are measured before and after the time of the follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902113840N1**
Registration date: **2010-05-21, 1389/02/31**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-21, 1389/02/31

Registrant information

Name

Mahdieh Hoseinzade Shamsi Anar

Name of organization / entity

Shahid Sadughi University of Medical Sciences and

Health Services

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Recruitment status

Recruitment complete

Funding source

1. Shahid Sadughi University of Medical Sciences and Health Services 2. Yazd Diabetes Research Center

Expected recruitment start date

2010-01-25, 1388/11/05

Expected recruitment end date

2010-03-01, 1388/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation on glucose status, lipid profiles and inflammatory factors in mothers with a history of gestational diabetes

Public title

Effect of vitamin D on diabetes prevention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: women with gestational diabetes at their recent pregnancy from the list of GDM Diabetes Research Center of Yazd University, and without thyroid disease, kidney disease, bone disease, PCO, liver disease and not using anti-epilepsy drugs, glucocorticoids, and statins. Exclusion criteria: risk of any illness that requires medication and lack of any willingness to cooperate.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **44**

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**

Shahid Sadughi University of Medical Sciences and Health Services

Street address

Second Central Building of Shahid Sadughi University of Medical Sciences and Health Services, Shahid Bahonar square

City

Yazd

Postal code

891697847

Approval date

empty

Ethics committee reference number

118104/1/17/پ

Health conditions studied**1****Description of health condition studied**

Gestational diabetes mellitus

ICD-10 code

O24

ICD-10 code description

Diabetes mellitus in pregnancy

2**Description of health condition studied**

Diabetes mellitus

ICD-10 code

E11, E12

ICD-10 code description

Insulin-dependent diabetes mellitus, Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

cytokines effective in diabetes

Timepoint

Before and 3 months after intervention

Method of measurement

ELIZA kit

2**Description**

Blood Glucose and lipid

Timepoint

Before and 3 months after intervention

Method of measurement

ELIZA

Secondary outcomes**1****Description**

Insulin resistance

Timepoint

Before and 3 months after intervention

Method of measurement

ELIZA kit

Intervention groups**1****Description**

Intervention: intramuscular injection of vitamin D with 300,000 international units dose

Category

Treatment - Drugs

2**Description**

Control: not receive any complementary

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yazd Diabetes Research Center

Full name of responsible person
Street address
City
Yazd

msalaami@hotmail.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Sadughi University of Medical Sciences and Health Services
Full name of responsible person
Hassan Mozaffari
Street address
3rd floor, Central Building of Shahid Sadughi University of Medical Sciences and Health Services, Shahid Bahonar sq.
City
Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadughi University of Medical Sciences and Health Services

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
Shahid Sadughi University of Medical Sciences and Health Services
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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