

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The Impact of Vitamin D Supplementation in Gestational Diabetes Cases on Post-Partum Glucose Tolerance and Insulin Resistance: A Randomized Controlled Trial

Protocol summary

valizadeh@zums.ac.ir

Summary

Study goal:determining the effect of vitamin D deficiency treatment during pregnancy on post partum glucose tolerance test. study design:randomized , with control. inclusion criteria:gestational diabetes, singleton pregnancies , vitamin D deficient women older than 16 who filled the patient's informed consent. exclusion criteria: women who does not eat take vitamin D pearls and does not fill the informed consent. sample size:110 interventions: taking 14 pearls of 50000 IU vitammin D intervention time: 12- 32 weeks of pregnancy. first outcome: Decrease rate of DM, IFG anf IGT at 6-12 weeks after delivery

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2012-10-23, 1391/08/02

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101611144N1**

Registration date: **2012-10-24, 1391/08/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-24, 1391/08/03

Registrant information

Name

Dr. Majid Valizadeh

Name of organization / entity

Zanjan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 24 1727 0714

Email address

Scientific title

The Impact of Vitamin D Supplementation in Gestational Diabetes Cases on Post-Partum Glucose Tolerance and Insulin Resistance: A Randomized Controlled Trial

Public title

Gestational diabetes and vitamin D

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: gestational diabetes, singleton pregnancies , vitamin D deficient women older than 16 who filled the patient's informed consent. Exclusion criteria: 1- women with overt diabetes. 2- fat malabsorbtion 3- vitamin D injection or taking vitamin D pearls with high dose(6 or more pearls of 50000 IU viamin D) in last 3 months. 4- hypothyroidism or hyperthyroidism 5- hypertension. 6- unwillingness to fill the testimonial. 7- not using the pearls

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

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

Zanjan University of Medical Sciences

Street address

Zanjan, Azadi Boulevard, Zanjan university of Medical Science

City

Zanjan

Postal code

Approval date

2012-10-13, 1391/07/22

Ethics committee reference number

A-11-45-7

Health conditions studied

1

Description of health condition studied

Gestational diabetes

ICD-10 code

O24.4

ICD-10 code description

Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description

Glucose tolerance test

Timepoint

6-12 weeks after delivery

Method of measurement

blood glucose level

Secondary outcomes

1

Description

Insulin resistance

Timepoint

6-12 weeks after delivery

Method of measurement

HOMA-IR calculation

Intervention groups

1

Description

Control group: blood glucose, vitamin D and Ca measurement.

Category

N/A

2

Description

vitamin D, pearl 50000 IU, at first taking 4 pearls in 2 days following (2 for each day) and then weekly. In the cases more than 30 weeks, weekly 2 pearls

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Education and treatment center of Valieasr

Full name of responsible person

Street address

City

Zanjan

2

Recruitment center

Name of recruitment center

Education and treatment center of Musavi

Full name of responsible person

Street address

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person
Dr. Alireza Biglari
Street address
Zanjan University of Medical Science, Azadi boulevard,
Zanjan
City
Zanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Sciences
Proportion provided by this source
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

2

Sponsor

Name of organization / entity
Added at 2014-04-13: :ARKRAY company
Full name of responsible person
Added at 2014-04-13: Farir TEB
Street address
Added at 2014-04-13: Farir Asa Teb No.64, Mehrshad
St., Saeedi St., Afriqa Blvd., Tehran, Iran
City
Added at 2014-04-13: Tehran
Grant name
1393/1/24 پروژرسانی:
Grant code / Reference number
Added at 2014-04-13: -
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Added at 2014-04-13: :ARKRAY company
Proportion provided by this source
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
Zanjan University of Medical Sciences

Full name of responsible person
Zahra Piri
Position
MD student
Other areas of specialty/work
Street address
Metabolic Disease Research Center, Valieasr hospital,
Sheikh Fazlollah Nouri Blvd, Zanjan
City
Zanjan
Postal code
Phone
+98 24 1727 0714
Fax
Email
zahra.piri@gmail.com; zahra.piri@rocketmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Majid Valizadeh
Position
Associate professor, Endocrinologist
Other areas of specialty/work
Street address
Research Associate Principal, Metabolic Disease
Research Center, Valieasr hospital, Sheikh Fazlollah
Nouri Blvd, Zanjan
City
Zanjan
Postal code
Phone
+98 24 1727 0714
Fax
+98 24 1727 0715
Email
valizadeh@zums.ac.ir; mvalizadeh47@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Zahra Piri
Position
MD student
Other areas of specialty/work
Street address
Metabolic Disease Research Center, Valieasr hospital,
Sheikh Fazlollah Nouri Blvd, Zanjan
City
Zanjan
Postal code
Phone
+98 24 1727 0714

Fax

+98 24 1727 0715

Email

zahra.piri@gmail.com; zahra.piri@rocketmail.com

Web page address

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