Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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:gestattional 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

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

valizadeh@zums.ac.ir

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

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: gestattional 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- unwiliingness to fill the testiomonial. 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 2days 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 boulvard, 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 بروزرسانی:
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
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Person responsible for scientific inquiries

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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