Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of 50000 IU Vitamin D supplement administered two weekly on neonatal and pregnant women outcome

Protocol summary

Summary

This study is a Randomized clinical trial conducted on 440 pregnant women who referred to pregnancy clinic of Shahid Sadoughi and Mojibian parathyroid Hospitals. The study population were randomly divided in two groups. Case group received 50000 IU of Vitamin D every 2 weeks and control group received 200 IU vitamin D3 daily. Blood samples were taken after 8 hours fasting. After serum extraction, samples were stored at _70 C until collection of all samples to measurement of serum 25-OHD. For all pregnant women screening for diabetes with a 75 gr oral glucose tolerance test and in 0, 1 & 2 hours (GTT) were done, Subjects with plasma glucose concentrations of one or more than 92 in 0, 180 in 1 & 153 in 2 hours were assumed positive for gestational diabettes. Inclusion criteria: all pregnant women came to prenatal clinic of Shahid Sadoughi and Mojibian Hospitals during first trimester with no history of corticosteroids or anticonvulsants use during the last 6 months were involved after blood sample taken for measurement of vitamin D serum level and were randomly assigned to two groups Exclusion criteria any person with history of thyroid or parathyroid diseases, receiving vitamin D more than maintenance dose during last 6 months, treated with corticosteroids or anticonvulsants and history of diabetes mellitus before pregnancy.

General information

Acronym

GDM

IRCT registration information

IRCT registration number: **IRCT201107237097N1**
Registration date: **2012-02-27, 1390/12/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-02-27, 1390/12/08

Registrant information

Name
Mahdiyeh Mojibian
Name of organization / entity
Obstetric and Gynecology department
Country
Iran (Islamic Republic of)
Phone
+98 35 1822 4000
Email address
m.mojibian@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadughi Yazd University of Medical Sciences

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 50000 IU Vitamin D supplement administered two weekly on neonatal and pregnant women outcome

Public title

The effect of 50000 IU Vitamin D supplement administered two weekly on gestational Diabetes Melitus

Purpose

Prevention

Inclusion/Exclusion criteria

All pregnant women who came to prenatal clinic of Shahid Sadoughi and Mojibian Hospitals during first trimester with no history of corticosteroids or anticonvulsants use during the last 3 months were included. Exclusion criteria: history of thyroid or parathyroid diseases; receiving vitamin D more than maintenance dose during the last 6 months; treatment with corticosteroids or anticonvulsants and history of diabetes mellitus before pregnancy.

Age
From **15 years** old to **48 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **440**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Sadughi Yazd University of Medical Sciences

Street address
Bahonar SQ - Yazd

City
Yazd

Postal code

Approval date
2011-06-26, 1390/04/05

Ethics committee reference number
39312

Health conditions studied

1

Description of health condition studied
Gestational DM

ICD-10 code
O24.4

ICD-10 code description
Gestational diabetes mellitus NOS

2

Description of health condition studied
VitD deficiency

ICD-10 code
E55.9

ICD-10 code description
Vitamin D deficiency, unspecified

Primary outcomes

1

Description
Vit D

Timepoint
First trimester

Method of measurement
Blood sample test

Secondary outcomes

1

Description
Gestational DM

Timepoint
First trimester

Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: vitamin D supplement, 50000u tab, every 2 weeks

Category
Prevention

2

Description
Control group: vitamin D Supplement, Calcium-D tablet, 200 IU daily

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Baghaipour Clinic

Full name of responsible person
Mrs Naghshin

Street address

City
Yazd

2

Recruitment center
Name of recruitment center
Gynecology Clinic of Mojibian Hospital
Full name of responsible person
Dr Maryam Jannati Moghaddam
Street address
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadughi Yazd University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Ezoddini
Street address
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 Yazd 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
Dr Mojibian hospital
Full name of responsible person
Dr Maryam Jannati Moghadam
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Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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Shahid Sadoughi Univercity of Medical Sceince- Yazs diabetics research center
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Person responsible for updating data

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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