

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

comparison of effectiveness of Vitamin D supplementation in decreasing the development of the gestational diabetes mellitus in pregnant women

Protocol summary

Summary

The goal of this study is determining the efficiency of therapeutic dose of vitamin D in preventing occurrence of gestational Diabetes Mellitus. The main including criteria are : 1) Patient desire 2) Gestational age below 16 weeks 3) No history of diabetes mellitus type 2 or gestational Diabetes Mellitus 4) No family history of Diabetes Mellitus type 1 in first degree relatives 5) Obesity The main excluding criteria are: 1) Patient dissatisfaction and discontinuation of follow up 2) incorrect consumption of vitamin D The study was performed on three groups of 75 pregnant women referring to obstetric clinic of Shahid Beheshti and Alzahra hospital in Esfahan city in 2012 (overall 225 persons) At first, the level of serum vitamin D is measured between 14 to 16 weeks of gestation. Persons with level of below 10 nmol per liter are divided to groups A and B, randomly. Group A are treated with vitamin D supplementation with dose of 50000 unit every two weeks for ten weeks. Group B are not treated with vitamin D supplementation. Among persons with level of above 25 nmol per liter, 75 persons were selected as normal healthy control group. At the end of the study between 24 to 26 weeks of gestation the oral glucose tolerance test was performed in groups A and B (as consumption of 75 gram oral glucose and measurement of blood glucose level 1 and 2 hours later). First hour post-prandial glucose level more than 180 mg per dl and second hour level more than 155 mg per dl or FBS above 95 are considered as impaired glucose tolerance test. Also these two groups are compared with normal control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309277513N4**

Registration date: **2014-01-03, 1392/10/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-03, 1392/10/13

Registrant information

Name

Hatav Ghasemi Tehrani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 113 4081

Email address

tehrani@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of effectiveness of Vitamin D supplementation in decreasing the development of the gestational diabetes mellitus in pregnant women

Public title

comparison of effectiveness of Vitamin D supplementation in decreasing the development of the gestational diabetes mellitus in in pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Including Criteria patient satisfaction; normal BMI; gestational age below 16w,s; no history of diabetes mellitus type 2 or gestational diabetes mellitus ; no family history of Diabetes Mellitus type 1 in first degree relatives. Excluding Criteria patient dissatisfaction; Incorrect Consumption of Vitamin D Supplementation; Follow up discontinuation

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

N/A

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

Department of Obstetrics and Gynecology

Street address

Alzahra hospital (Isfahan)

City

Isfahan

Postal code

Approval date

2013-08-20, 1392/05/29

Ethics committee reference number

392391

Health conditions studied

1

Description of health condition studied

Gestational Diabetes Melitus

ICD-10 code

O24.4

ICD-10 code description

Diabetes, diabetic (mellitus) (controlled) (familial) (severe) - arising in pregnancy O24.4

Primary outcomes

1

Description

Gestational blood sugar level

Timepoint

Gestational age 14 to 16 weeks: serum Vitamin D level / 24 to 26 weeks: Serum blood sugar level and glucose tolerance test

Method of measurement

Based on laboratory test for vitamin D and blood sugar level

Secondary outcomes

empty

Intervention groups

1

Description

The study was performed on three groups of 75 pregnant women referring to obstetric clinic of Shahid Beheshti and Alzahra hospital in Esfahan city in 2012 (overall 225 persons) At first, the level of serum vitamin D is measured between 14 to 16 weeks of gestation. Persons with level of below 10 nmol per liter are divided to groups A and B, randomly. Group A are treated with vitamin D supplementation with dose of 50000 unit every two weeks for ten weeks. Group B are not treated with vitamin D supplementation. Among persons with level of above 25 nmol per liter, 75 persons were selected as normal healthy control group. At the end of the study between 24 to 26 weeks of gestation the oral glucose tolerance test was performed in groups A and B (as consumption of 75 gram oral glucose and measurement of blood glucose level 1 and 2 hours later). First hour post-prandial glucose level more than 180 mg per dl and second hour level more than 155 mg per dl or FBS above 95 are considered as impaired glucose tolerance test. Also these two groups are compared with normal control group.

Category

Prevention

2

Description

Control group Pregnant women with 14 to 16 weeks of gestational age with serum vitamin D level above 25 nmol/liter

Category

Prevention

3

Description

Study groups 1- Pregnant women with gestational age of 14 to 16 weeks with serum vitamin D level below 10 nmol per liter without vitamin D supplementation 2- Pregnant women with gestational age of 14 to 16 weeks with serum vitamin D level below 10 nmol per liter treated with vitamin D supplementation as 50000 unit dosage every 2 weeks for 10 weeks

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan, Shahid Beheshti hospital and Alzahra Hospital

Full name of responsible person

Behnaz Banihashemi

Street address

Num 7 Parastoo building, Between south Resalat and Farabi ave, Sheikh Koleini st, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University Of Medical Sciences

Full name of responsible person

Dr. Hatav Ghasemi Tehrani

Street address

Isfahan- Alzahra Hospital- Gynecology Department

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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

Isfahan University Of Medical Sciences

Full name of responsible person

Dr. Hatav Ghasemi Tehrani

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan University Of Medical Sciences

Full name of responsible person

DR. Behnaz Banihashemi

Position

Gynecology Resident

Other areas of specialty/work

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Email
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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