Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of vitamin D administration in preventing and controlling gestational diabetes and neonatal outcomes

Protocol summary

Study aim

The effect of vitamin D administration on prevention of gestational diabetes and improvement of blood glucose in these individuals and evaluation of changes in neonatal outcomes

Design

In this randomized clinical trial study, 100 patients were randomly divided into two groups using random allocation software, the first group will receive 1000 units of vitamin D daily and the second group will receive 3000 units of vitamin D daily. Serum vitamin D3 levels are monitored at baseline, once a week for 24-28 weeks, along with glucose tolerance testing and once for 35-37 weeks, and all patients will be followed up until delivery. Both groups will be monitored for neonatal outcomes, including NICU admission, birth weight, and type of delivery.

Settings and conduct

This study will be performed on patients referring to Imam Hossein Hospital in Tehran on a single-blind basis. Blindness is such that patients are unaware of the type of vitamin D medication and only the physician will be aware of the therapeutic dose.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All mothers in the first trimester Having a risk factor for gestational diabetes (including a previous history of gestational diabetes, high body mass index, diabetes type 2 in the first degree family and a history of macrosomal infant birth) Having informed consent in a pregnant mother Exclusion criteria: Impaired glucose of mothers in the first trimester Evidence of overt diabetes

Intervention groups

Group 1: daily intake of 1000 units of vitamin D Group 2: Daily intake of 3000 units of vitamin D

Main outcome variables

Vitamin D3 levels at baseline and 24-28 weeks of gestation; Testing for glucose tolerance at baseline and 24-28 weeks and one time at 35-37 weeks of gestation; Neonatal outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N34**
Registration date: **2019-08-28, 1398/06/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-28, 1398/06/06**
Update count: **0**

Registration date

2019-08-28, 1398/06/06

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3629 1510

Email address

mehrabi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy of vitamin D administration in preventing and controlling gestational diabetes and neonatal outcomes

Public title
The effect of vitamin D on the treatment of gestational diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All mothers in the first trimester Having a risk factor for gestational diabetes (including a previous history of gestational diabetes, high body mass index, diabetes type 2 in the first degree family and a history of macrosomal infant birth) Having informed consent in a pregnant mother
Exclusion criteria:
Impaired glucose of mothers in the first trimester Evidence of overt diabetes
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
After entering the study, 100 patients were randomly divided into two groups of 50 each.
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
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2018-11-20, 1397/08/29
Ethics committee reference number
IR.SBMU.MSP.REC.1397.791

Health conditions studied

1

Description of health condition studied
Gestational diabetes
ICD-10 code
O24.9
ICD-10 code description
Unspecified diabetes mellitus in pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Vitamin D Level 3
Timepoint
baseline and 24-28 weeks of gestation
Method of measurement
Serum samples from patients using ELISA method

2

Description
Glucose tolerance test
Timepoint
baseline and 24-28 weeks and one time at 35-37 weeks of gestation
Method of measurement
Evaluation of blood glucose in patients at 0, 1, 2, 3 hours after consumption of 100 g glucose

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: recipient of the 1000 IU vitamin D daily
Category
Treatment - Drugs

2

Description

Intervention group: recipient of the 3000 IU vitamin D daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital

Full name of responsible person

Nooshin Amjadi

Street address

Imam Hossein Hospital, Shahid Madani Ave, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarqi

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7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nooshin Amjadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Ali Mehrabi Koushki

Position

Epidemiologist

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Position
Epidemiologist

Latest degree
Master

Other areas of specialty/work
Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The data belongs to the government agency.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Because the study data is related to the government organization, there is no way to share it

When the data will become available and for how long
any time

To whom data/document is available
any person

Under which criteria data/document could be used
Under no circumstances

From where data/document is obtainable
any person

What processes are involved for a request to access data/document
any procedure

Comments