

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of vitamin D supplement during pregnancy on umbilical cord vitamin D, bone mineral density and anthropometric measurements from birth to two months later

Protocol summary

Summary

The objective of the study is to investigate the effects of vitamin D supplementation during pregnancy on umbilical cord vitamin D, bone mineral density and anthropometric measurements from birth to two months later. Pregnant women at 26 to 28 weeks of gestation, having a singleton and alive fetus, healthy and without medical history, free of any complication of pregnancy and no previous cesarean section are invited to participate in this study. The intervention group are given 2000 IU of vitamin D3 daily as tablet until the end of pregnancy, while the control group receive placebo until delivery time. If a participant receive vitamin D supplementation or placebo less than 8 weeks, her newborn will be excluded from the study. After birth cord blood sample for 25-hydroxy vitamin D concentration is collected in the participants as far as possible. Weight, head circumference and height of the newborn are measured at birth, 4 and 8 weeks after birth. Infant bone mineral density is measured by dual-energy X-ray absorptiometry up two months after birth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040910327N13**
Registration date: **2015-07-21, 1394/04/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-21, 1394/04/30

Registrant information

Name

Farideh Vaziri

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 9131

Email address

vazirif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of vitamin D supplement during pregnancy on umbilical cord vitamin D, bone mineral density and anthropometric measurements from birth to two months later

Public title

Effects of vitamin D supplement during pregnancy on umbilical cord vitamin D, bone mineral density and anthropometric measurements from birth to two months later

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate in the study; aged 18 years or older; at 26- 28 weeks gestation based on ultrasound; alive and singleton fetus; without a history of cesarean section; without a history of any disease; free of complication in present pregnancy; Exclusion criteria: cancellation of continuing the cooperation by the participants; taking vitamin D supplements less than 8 weeks ; nonhealthy newborn; newborn with any gross anomaly

Age

To **2 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Allocation of the participant into the intervention or control group will be performed through block randomization method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Science Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Postal code

Approval date

2015-04-19, 1394/01/30

Ethics committee reference number

IR.SUMS.REC.1394.6

Health conditions studied

1

Description of health condition studied

Bone densitometry

ICD-10 code

E35.8

ICD-10 code description

Disorders of other endocrine glands in diseases classified elsewhere

Primary outcomes

1

Description

blood cord vit D concentration

Timepoint

After Delivery

Method of measurement

ELISA or another available method

2

Description

Bone densitometry

Timepoint

during first two months after birth

Method of measurement

Radiology and DXA method

3

Description

Antropometric measurements (height, weight and head circumference)

Timepoint

At birth, at 4 and 8 weeks later

Method of measurement

Metric system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 2000 IU of vitamin D3 from 26-28 weeks gestation daily until delivery

Category

Prevention

2

Description

control group: placebo from 26-28 weeks gestation daily until delivery or routine care

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez hospital

Full name of responsible person

Farideh Vaziri

Street address

Chamran boulevard

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Basir Hashemi

Street address

Zand street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Farideh Vaziri

Position

Master's degree in Midwifery, Faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dr Hossein Dabaghmanesh

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Medical Doctor, Faculty member

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Person responsible for updating data

Contact

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Full name of responsible person

Farideh Vaziri

Position

Other areas of specialty/work

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City

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Fax

Email

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