

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Determination of the effects of monthly consumption of 100000 unit cholecalciferol during third trimester on plasma iPTH and 25 (OH) D3 of the mother and offspring in a group of pregnant Tehranian women and a matched control group.

Protocol summary

Summary

The present study was designed to investigate the effects of monthly 100.000 IU of vitamin D on 25(OH) VitD and iPTH status in mothers and their newborns. Total of 50 pregnant women at 27 - 28 weeks of gestational age were randomly allocated into equal groups of intervention and placebo. All patients with sarcoidosis, tuberculosis, known liver and renal ($cr > 2$) disease, use of vitamin D and anticonvulsant drugs, were excluded. The patients were randomly allocated into one of two groups. One group received 100.000 IU vitamin D, one dose, monthly and others received the same capsules as placebo. 25(OH) Vit D, iPTH were measured at the beginning and the end of the study from the mother and cord blood. 25(OH)Vit D, iPTH were measured at the beginning and the end of the study from the mother and cord blood.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104306335N1**

Registration date: **2011-06-19, 1390/03/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-19, 1390/03/29

Registrant information

Name

Zary Sabet

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 6130

Email address

sabet@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for endocrine research, Shahid Beheshty University of Medical Sciences

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2010-06-22, 1389/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of the effects of monthly consumption of 100000 unit cholecalciferol during third trimester on plasma iPTH and 25 (OH) D3 of the mother and offspring in a group of pregnant Tehranian women and a matched control group.

Public title

Effects of monthly consumption of 100000 unit cholecalciferol during last third trimester of pregnancy on plasma iPTH and 25 (OH) D3 of the mother and cord blood

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women whose gestational age was between 27 to 28 weeks. Exclusion criteria: Patients with systemic diseases such as renal (Cr > 2) and known liver disease, sarcoidosis, tuberculosis and receiving of vit D and anticonvulsant drugs.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

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, Endocrine Research Center

Street address

p.o.box: 1985717413, Endocrine Research Center, Shahid Beheshti University of Medical Sciences, NO 24, Parvaneh St, Yaman St, Chamran EXP way, Tehran, Iran.

City

Tehran

Postal code

1985717413

Approval date

2009-04-27, 1388/02/07

Ethics committee reference number

254EC

Health conditions studied

1

Description of health condition studied

Vit D

ICD-10 code

P00.4

ICD-10 code description

Fetus and newborn affected by maternal nutritional disorders

Primary outcomes

1

Description

25(OH)Vit D

Timepoint

3 months

Method of measurement

Laboratory methods(ng/ml)

2

Description

iPTH

Timepoint

3 months

Method of measurement

Laboratory methods(Pmol/l)

Secondary outcomes

empty

Intervention groups

1

Description

Cholecalciferol (Vitamin D3), capsule 50.000 IU, two capsules monthly for 3 months

Category

Treatment - Drugs

2

Description

Distilled water capsule, two capsules monthly for 3 months in last trimester of pregnancy

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghany Hospital -Beheshti University

Full name of responsible person

Zary Sabet

Street address

Taleghany Hospital, Parvaneh St, Yaman St, Chamran EXP way, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for endocrine research, Shahid Beheshty University of Medical Sciences

Full name of responsible person

Saleh Zahedi Asl

Street address

p.o.box: 1985717413, Vice chancellor for endocrine research, Shahid Beheshty University of Medical Sciences, NO 24, Parvaneh St, Yaman St, Chamran EXP way, Tehran, Iran.

City

Tehran

Grant name

جاری و سایر منابع

Grant code / Reference number

123807

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

Yes

Title of funding source

Vice chancellor for endocrine research, Shahid Beheshty 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**

Shahed University

Full name of responsible person

Zary Sabet

Position

Endocrinologist/Assistant Professor

Other areas of specialty/work**Street address**

p.o.box: 14166, Mostafa Khomeiny Hospital, Itali St, Felestin St, Tehran, Iran.

City

Tehran

Postal code

14166

Phone

+98 21889661309

Fax

+98 21 8896 3739

Email

sabet@shahed.ac.ir; sabet@safineh.net

Web page address

www.shahed.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahed University

Full name of responsible person

Dr Zary Sabet

Position

Endocrinologist

Other areas of specialty/work**Street address**

p.o.box: 14166, Mostafa Khomeiny Hospital, Itali St, Felestin St, Tehran, Iran.

City

Tehran

Postal code

14166

Phone

+98 21 8896 6131

Fax

+98 21 8896 3739

Email

sabet@shahed.ac.ir

Web page address

www.shahed.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Shahed University

Full name of responsible person

Zary Sabet

Position

Endocrinologist/Assistant Professor

Other areas of specialty/work**Street address**

p.o.box: 14166, Mostafa Khomeiny Hospital, Itali St, Felestin St, Tehran, Iran.

City

Tehran

Postal code

14166

Phone

+98 21 8824 0193

Fax

+98 21 8896 3739

Email

sabet@shahed.ac.ir; sabet@safineh.net

Web page address

www.shahed.ac.ir

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