Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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(0H)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 -Beheshty 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