

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effects of vitamin D supplementation on thyroid function tests in pregnant women

Protocol summary

Summary

The objective of the study is to investigate the effects of vitamin D supplementation during pregnancy on functional thyroid tests like TSH, Free T4, Anti TPO antibody, Anti TG antibody. 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, she will be excluded from the study. Blood samples will be collected for the abovementioned thyroid tests before intervention and during first 24 hours after delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508091312N2**

Registration date: **2015-09-02, 1394/06/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-02, 1394/06/11

Registrant information

Name

Mohammad Hossein Dabbaghmanesh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1230 8728

Email address

dabbaghm@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 supplementation on thyroid function tests in pregnant women

Public title

Effects of vitamin D supplementation on thyroid function tests in pregnant women

Purpose

Other

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

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Postal code

Approval date

2015-08-02, 1394/05/11

Ethics committee reference number

IR.SUMS.REC.1394.87

Health conditions studied

1

Description of health condition studied

Variation in thyroid tests in pregnancy

ICD-10 code

E06.3

ICD-10 code description

Autoimmune thyroiditis

Primary outcomes

1

Description

TSH level

Timepoint

Before intervention and first 24 hours after birth

Method of measurement

ELISA

2

Description

T4 level

Timepoint

Before intervention and first 24 hours after birth

Method of measurement

ELISA

3

Description

Anti TPO antibody

Timepoint

Before intervention and first 24 hours after birth

Method of measurement

ELISA

4

Description

Anti TG antibody level

Timepoint

Before intervention and first 24 hours after birth

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

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

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez hospital

Full name of responsible person

Farideh Vaziri

Street address

Zand street

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

Dr Mohammad Hossien Dabbaghmanesh

Position

Medical Doctor, Endocrinologist, Faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Other areas of specialty/work

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+98 36672254

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roose82003@yahoo.com

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