

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effect of vitamin D supplement in pregnancy on prevention of postpartum depression

Protocol summary

Summary

The present study has been designed to investigate the effect of vitamin D supplementation on prevention of postpartum depression. This clinical trial is conducted on 148 pregnant women who may be nulliparous or multiparous. 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. Depression score of each participant is determined using the Edinburgh Postnatal Depression Scale and if it is greater than 13, the participant is excluded and referred to a psychiatrist. Participants are assigned in the intervention and the control groups by block randomization method. Before starting the interventions, blood sample for 25-hydroxy vitamin D concentration is collected in all of the participants. The intervention group are given 2000 IU of vitamin D 3 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. Depression score of the participants will be determined between 38 to 40 weeks gestation, four and eight weeks after delivery again. Also maternal serum 25-hydroxy vitamin D concentration will be measured at delivery. The depression scores in late pregnancy, at four and eight weeks after delivery in the intervention and control groups will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020310327N11**

Registration date: **2015-03-09, 1393/12/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-09, 1393/12/18

Registrant information

Name

Farideh Vaziri

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

2015-07-21, 1394/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplement in pregnancy on prevention of postpartum depression

Public title

Effect of vitamin D supplement in pregnancy on prevention of postpartum depression

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:the score of Edinburgh Postnatal Depression Scale at beginning of the study is more than 13; cancellation of continuing the cooperation by the participants; less than 8 weeks taking vitamin D supplements or placebo

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **148**

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

Ethic commity of shiraz university of medical sciences

Street address

Zand street

City

Shiraz

Postal code

Approval date

2014-11-19, 1393/08/28

Ethics committee reference number

7212_93

Health conditions studied

1

Description of health condition studied

postpartum depression

ICD-10 code

F-53.0

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description

Postpartum depression

Timepoint

Four and eight weeks after delivery

Method of measurement

Edinburgh Postnatal Depression Scale

Secondary outcomes

1

Description

Serum 25-hydroxy vitamin D concentration

Timepoint

Before starting the interventions and at delivery

Method of measurement

Alisa or HPLC method

2

Description

Late pregnancy depression

Timepoint

at 38- 40 weeks gestation

Method of measurement

Edinburgh Postnatal Depression Scale

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

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Miss Samira Nasiri

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

Gholam Reza Hatam

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7th Floor, Shiraz University of Medical Sciences, 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

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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*