Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Farideh Vaziri
Name of organization / entity
Shiraz University of Medical Sciences
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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
Street address
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
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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