

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of vitamin D3 and calcium supplementation on depression severity, levels of 25-hydroxy vitamin D, sex hormone estradiol and inflammatory biomarkers (Interleukin 6, Tumor Necrosis Factor alpha) in women with postpartum depression

Protocol summary

Summary

Objectives: The purpose of this study is to evaluate the effect of vitamin D3 and calcium supplementation on levels of 25-hydroxy vitamin D, sex hormone estradiol and inflammatory biomarkers (Tumor Necrosis Factor alpha, Interleukin 6) and depression severity, in women with postpartum depression. **Design:** This study is a randomized, double-blind controlled randomized trial with 8 weeks period. **Setting and conduct:** Eighty one patients with postpartum depression and serum vitamin D levels less than normal range, with consecutive sampling method, will be selected from the Health Center number 1, located in the West of the Ahvaz city. Edinburgh questionnaire will be used to evaluate clinical symptoms. Questionnaires at baseline and every 2 weeks for 8 weeks will be completed by the patients. **Major Inclusion criteria:** Score of 12 and above from Edinburgh questionnaire; a period range from 1 month until 6 months after child birth. **Major Exclusion criteria:** Vitamin D levels to normal or above normal range; chronic diseases. **Intervention:** The subjects will be divided into 3 groups based on randomized block design: group 1 will receive 50000 units vitamin D3, every 14 days and one calcium carbonate tablet (500 milligram, daily), group 2 will receive 50000 units vitamin D3, every 14 days and one calcium placebo (500 milligram, daily), group 3 (control group) will receive vitamin D3 placebo contains edible paraffin, every 14 days and calcium placebo (daily), for 8 week. **Main outcome variables:** Depression severity will be measured, using Edinburgh questionnaire. Biochemical measurements (serum levels of 25-hydroxy vitamin D and calcium, inflammatory factors (Interleukin 6 and Tumor Necrosis Factor alpha) and estradiol will be measured using ELISA assay.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016091416123N9**

Registration date: **2017-05-21, 1396/02/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-21, 1396/02/31

Registrant information

Name

Sima Jafarirad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-07-05, 1396/04/14

Expected recruitment end date

2017-08-24, 1396/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D3 and calcium supplementation on depression severity, levels of 25-hydroxy vitamin D, sex hormone estradiol and inflammatory biomarkers (Interleukin 6, Tumor Necrosis Factor alpha) in women with postpartum depression

Public title

The effect of vitamin D3 and calcium supplementation in treatment of postpartum depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Body mass index (BMI) less than 35; age 18 to 45 years; earning a score of 12 and above in Edinburgh questionnaire; period range from 1 month until 6 months after child birth. Exclusion criteria: Normal or above normal range for vitamin D levels; chronic diseases such as diabetes, renal failure, gastrointestinal diseases, liver, thyroid, kidney stones and cancer in the past 5 years; birth abnormalities; taking contraceptive drugs; endocrine disorders; severe depression and other mental disorders; using antidepressants.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **81**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan, Ahvaz, Iran

City

Ahvaz

Postal code**Approval date**

2017-04-23, 1396/02/03

Ethics committee reference number

IR.AJUMS.REC.1396.59

Health conditions studied**1****Description of health condition studied**

Post partum depression

ICD-10 code

F53.0

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium

Primary outcomes**1****Description**

Tumor Necrosis Factor alpha

Timepoint

Before and after of 8 weeks intervention

Method of measurement

seum level

2**Description**

Interleukin 6

Timepoint

Before and after of 8 weeks intervention

Method of measurement

seum level

3**Description**

Estradiol

Timepoint

Before and after of 8 weeks intervention

Method of measurement

seum level

4**Description**

25 Hydroxy Vitamin D
Timepoint
Before and after of 8 weeks intervention
Method of measurement
seum level

5

Description
Depression severity
Timepoint
Baseline and every 14 days for 8 weeks
Method of measurement
Edinburgh questionnaire

6

Description
Serum calcium
Timepoint
Before and after of 8 weeks intervention
Method of measurement
seum level

Secondary outcomes

1

Description
Weight
Timepoint
Before the intervention, end of the fourth week and end of the eighth week
Method of measurement
Scales

2

Description
Body Fat Percentage
Timepoint
Before the intervention, end of the fourth week and end of the eighth week
Method of measurement
Fat analyzer

3

Description
Waist Circumference
Timepoint
Before the intervention, end of the fourth week and end of the eighth week
Method of measurement
inflexible meter

4

Description
Body Mass Index
Timepoint
Before the intervention, end of the fourth week and end of the eighth week

Method of measurement
Using the formula

Intervention groups

1

Description
50000 IU pearl vitamin D3, every 14 days + 500 milligram calcium carbonate tablet, daily, for 8 weeks
Category
Treatment - Drugs

2

Description
50000 IU pearl vitamin D3, every 14 days + calcium carbonate placebo, daily, for 8 weeks
Category
Treatment - Drugs

3

Description
Pearl paraffin as vitamin D placebo, every 14 days + calcium carbonate placebo, daily, for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz West Health Center number 1
Full name of responsible person
Shirin amini
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz, Iran
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr.Makhmalzadeh
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Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz, Iran
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Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology, Ahvaz
Jundishapur 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

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Full name of responsible person

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Position

PhD candidate of Nutrition

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Other areas of specialty/work**Street 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