

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effect of vitamin D and calcium supplementation on serum levels of cortisol and inflammatory biomarkers (IL10, hsCRP) 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 sex hormone cortisol and inflammatory biomarkers Interleukin 10, high-sensitivity C-reactive protein (hsCRP), 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. In addition, the severity of anxiety will be examined by the Spielberger Questionnaire. 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 and calcium 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:** Biochemical measurements include serum levels of inflammatory factors (Interleukin 10, hsCRP) and cortisol will be measured using ELISA assay.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111016123N12**

Registration date: **2017-09-28, 1396/07/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-28, 1396/07/06

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

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-08-28, 1396/06/06

Expected recruitment end date

2017-09-28, 1396/07/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D and calcium supplementation on serum levels of cortisol and inflammatory biomarkers (IL10, hsCRP) in women with postpartum depression	2017-07-08, 1396/04/17 Ethics committee reference number IR.AJUMS.REC.1396.455
Public title Effect of vitamin D and calcium supplementation on serum levels of hormones affecting postpartum depression Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: Body mass index (BMI) less than 35; age 18 to 45years; 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; 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	Health conditions studied <u>1</u> Description of health condition studied F53.0 ICD-10 code F53.0 ICD-10 code description Mild mental and behavioural disorders associated with the puerperium Primary outcomes <u>1</u> Description Interleukin 10 Timepoint Before and after of 8 weeks intervention Method of measurement Seum level <u>2</u> Description Cortisol Timepoint Before and after of 8 weeks intervention Method of measurement Seum level <u>3</u> Description hsCRP Timepoint Before and after of 8 weeks intervention Method of measurement Seum level
Secondary Ids empty	Secondary outcomes
Ethics committees <u>1</u> Ethics committee Name of ethics committee Ahvaz Jundishapur University of Medical Sciences Street address Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz, Iran. City Ahvaz Postal code 6135715794 Approval date	<u>1</u> Description Severity of apparent (situational) and hidden (characteristic) anxiety Timepoint Baseline and every 14 days for 8 weeks Method of measurement Spill Burger Questionnaire <u>2</u> Description Blood pressure Timepoint

Before the intervention, end of the fourth week and end of the eighth week

Method of measurement

Pressure gauge

3

Description

Weight

Timepoint

Before the intervention, end of the fourth week and end of the eighth week

Method of measurement

Scales

4

Description

Serum calcium

Timepoint

Before and after of 8 weeks intervention

Method of measurement

Seum level

5

Description

Waist Circumference

Timepoint

Before the intervention, end of the fourth week and end of the eighth week

Method of measurement

Inflexible meter

6

Description

Depression severity

Timepoint

Baseline and every 14 days for 8 weeks

Method of measurement

Edinburgh questionnaire

7

Description

Estradiol

Timepoint

Before and after of 8 weeks intervention

Method of measurement

Seum level

8

Description

Body Mass Index

Timepoint

Before the intervention, the end of the fourth week and and the 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

Placebo

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 Blv, Ahvaz, Iran

City

Ahvaz

2

Recruitment center

Name of recruitment center

Sidon Health Center in Baghmalek City

Full name of responsible person

Shirin Amini

Street address

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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Makhmalzadeh

Street address

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

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sima Jafarirad

Position

PhD in Nutrition, Assistant Professor

Other areas of specialty/work

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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