

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of vitamin D supplementation in the prevention of recurrence of preeclampsia in pregnant women with a history of preeclampsia

Protocol summary

Summary

This study is a double blind clinical trial, and our goal is determining the effect of vitamin D supplementation on the occurrence of preeclampsia in pregnant women, who have a history of preeclampsia, previously. The participants are pregnant women, referred to the Besat clinic in Sanandaj city, who are enrolled in the study with informed consent. By using random assignment and table of random numbers, each patient is assigned to the intervention group or control group. Patients and researchers are unaware of the allocation of each patient. The number of participants is 142, this study is a single-center study and the third phase of clinical trial. Every two weeks, 50,000 units of vitamin D Perl is given to the intervention group, and placebo given to the control group. Zahravi pharmaceutical company is manufacturing the drug and placebo. Inclusion criteria is, having a history of preeclampsia, and blood level of vitamin D above 32 nanograms per milliliter following 12 hours of fasting, measured by Lieberman Bouchard method. The intervention is prescribing, Vitamin D. The main outcome is preeclampsia. Measurable variable of preeclampsia is, recording of sitting blood pressure above or equal to 140/90 mm Hg, and proteinuria in the urine test, is higher or equal to +1. Blood pressure every two weeks is measured in both groups. If blood pressure be equal or greater than 140/90 mm Hg, urine tests will be requested.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010131695N1**

Registration date: **2017-01-29, 1395/11/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-29, 1395/11/10

Registrant information

Name

Farnaz Zandvakili

Name of organization / entity

Kordestan medical university

Country

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Phone

+98 87 3366 4546

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Recruitment status

Recruitment complete

Funding source

This doctoral thesis gynecology and is supported by the Kurdistan University of Medical Sciences.

Expected recruitment start date

2017-01-09, 1395/10/20

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation in the prevention of recurrence of preeclampsia in pregnant women with a history of preeclampsia

Public title

The effect of vitamin D supplementation in the prevention of recurrence of preeclampsia in pregnant women with a history of preeclampsia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : pregnancy , history of preeclampsia in a previous pregnancy , blood levels of vitamin D above 32 nanograms per milliliter Exclusion criteria : the risk of chronic hypertension before pregnancy , chronic kidney disease associated pulmonary and cardiovascular , immunological diseases such as lupus , the uncertainty of patient cooperation in the study , immigration or study leave.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **142**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study, then matching the inclusion and exclusion criteria and obtaining informed consent, pregnant women were assigned to intervention and control groups randomly, by using random number table. Study participants are unaware of assignment in to the intervention or control groups. Physician is not aware of each patient's group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kurdistan University of Medical Science

Street address

Kurdistan University of Medical Sciences, Pasdaran Blvd. Sanandaj.

City

Sanandaj

Postal code

Approval date

2016-12-26, 1395/10/06

Ethics committee reference number

IR.MUK.REC.1395.266

Health conditions studied

1

Description of health condition studied

preeclampsia

ICD-10 code

O14.0 , O1

ICD-10 code description

Gestational [pregnancy-induced] hypertension with significant proteinuria Excl.: superimposed pre-eclampsia (O11) O14.0 Moderate pre-eclampsia O14.1 Severe pre-eclampsia

Primary outcomes

1

Description

Systolic and Diastolic blood pressure

Timepoint

In initiation of study, 2 week after intervention, per 2 week to termination of pregnancy

Method of measurement

Blood pressure is measured in the sitting position by using mercury barometer

2

Description

Proteinuria

Timepoint

If there is a blood pressure greater than or equal to 140/90 mm Hg.

Method of measurement

laboratory kit

Secondary outcomes

1

Description

Preeclampsia Recognition

Timepoint

After 28 weeks of pregnancy

Method of measurement

Measurement of blood pressure by using barometer, clinical symptoms and proteinuria detection by using laboratory kit

Intervention groups

1

Description

Intervention 1 : Administration of Vitamin D3, 50000 IU , pearl

Category

Prevention

2

Description

intervention 2: Administration of placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sanandaj Besat hospital

Full name of responsible person

Sanam Behjat Sasan

Street address

Besat Hospital, keshavarz Blvd, Sanandaj

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kurdistan University of Medical Sciences

Full name of responsible person

Mahin Zarei

Street address

Vice chancellor for research, Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj

City

Sanandaj

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, Kurdistan 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

Besat Hospital, Sannandaj

Full name of responsible person

Shole Shah Gheibi

Position

Head of department

Other areas of specialty/work

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Besat hospital, Keshavarz Blvd, Sanandaj

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Specialist medical doctor

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Person responsible for updating data

Contact

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Full name of responsible person

Sanam Behjat Sasan

Position

gynecology Resident

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