Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Iran (Islamic Republic of)
Phone
+98 87 3366 4546
Email address
zandvakili.f@muk.ac.ir

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
Street address
Besat hospital, Keshavarz Blvd, Sanandaj
City
Sanandaj
Postal code
66196-67761
Phone
+98 87 3328 2001
Fax
Email
shahgheibi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kurdestan University of Medical Science.
Full name of responsible person
Farnaz Zandvakili
Position
Specialist medical doctor
Other areas of specialty/work
Street address
Besat Hospital, Keshavarz Blvd, Sanandaj
City
Sanandaj
Postal code
66196-67761
Phone
+98 87 3328 2001
Fax
Email
Dr.zandvakili.f.@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kurdistan University of Medical Science
Full name of responsible person
Sanam Behjat Sasan
Position
gynecology Resident
Other areas of specialty/work
Street address
Kurdistan University of Medical Science, Pasdaran Blvd, Sanandaj
City
Sanandaj
Postal code
66117-13446
Phone
+98 87 3328 2001
Fax
Email

sanam.sasan@yahoo.com

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