Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the Impact of Vitamin D Supplementation with Placebo on Pre-eclampsia Prevention in Pregnant Women

Protocol summary

Study aim
Prevention of preeclampsia by taking vitamin D supplements
Design
Two-arm parallel group randomised trial with blinding
Settings and conduct
Gynecology department unit III of Nishtar Hospital, Multan
Participants/Inclusion and exclusion criteria
Patients who presented at the outpatient department of the hospital for prenatal care and had a previous history of preeclampsia during a previous pregnancy were included. Patients with renal insufficiency, cardiac disease, and hypertension before pregnancy, lack of confidence in cooperation, immunological disease and leaving during study were excluded
Intervention groups
In the intervention group, patients were given 50000 IU capsules of vitamin D3 once every 2 weeks.
Main outcome variables
Occurrence of Preeclampsia Type of delivery Abortion rate

General information

Reason for update
Acronym
PREV-D
IRCT registration information
IRCT registration number: **IRCT20230814059146N1**
Registration date: **2023-08-22, 1402/05/31**
Registration timing: **retrospective**

Last update: **2023-08-22, 1402/05/31**
Update count: **0**
Registration date
2023-08-22, 1402/05/31

Registrant information
Name
Saima Shahzad
Name of organization / entity
Nishtar Medical University
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Pakistan
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+92 300 7195857
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-01-19, 1400/10/29
Expected recruitment end date
2022-12-19, 1401/09/28
Actual recruitment start date
2022-01-19, 1400/10/29
Actual recruitment end date
2022-12-19, 1401/09/28
Trial completion date
2023-12-19, 1402/09/28

Scientific title
Comparing the Impact of Vitamin D Supplementation with Placebo on Pre-eclampsia Prevention in Pregnant Women

Public title
Effect of Vitamin D Supplement on Prevention of Preeclampsia in Pregnant Women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Presented with prenatal care in outpatient department previous history of Preeclampsia gestational age of >20 weeks

Exclusion criteria:
History of renal insufficiency History of cardiac disease History of hypertension before pregnancy lack of confidence in cooperation history of immunological disease patient willing to leave during trial

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **250**
Actual sample size reached: **250**

Randomization (investigator's opinion)
Randomized

Randomization description
stratfied simple random sampling technique, using random numbers first stratified by gender_

Blinding (investigator's opinion)
Single blinded

Blinding description
single blinding would involve ensuring that the participants (pregnant women) are unaware of whether they are receiving the actual Vitamin D supplementation or a placebo. This helps minimize bias and ensures that the results of the study are not influenced by the participants' or researchers' expectations or beliefs.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Institutional Ethical Review Board (IERB)

Street address
Nishtar Hospital, Multan

City
Multan

Postal code
66000

Approval date
2022-01-01, 1400/10/11

Ethics committee reference number
041

Health conditions studied

1

Description of health condition studied
Pre-eclampsia: The occurrence of hypertension in pregnancy after 20 weeks of gestation

ICD-10 code
014

ICD-10 code description
Pre-eclampsia

Primary outcomes

1

Description
Pre-eclampsia (Blood pressure measurement and proteinuria)

Timepoint
From 20 weeks till 36 weeks of gestation, (every two weeks)

Method of measurement
Blood pressure measurement using sphygmomanometer, and proteinuria by dipstick method

Secondary outcomes

1

Description
Type of delivery

Timepoint
At 40 weeks approximately

Method of measurement
Visual and medical record

2

Description
Abortion rate

Timepoint
From 20 weeks till abortion

Method of measurement
Based on history and medical records

Intervention groups

1

Description
Intervention group: In intervention group patients were given 50000 IU capsules of vitamin D3 once every 2 weeks. All patients were advised to take medicine (placebo or vitamin D) till 36 weeks of gestation. Preeclampsia was diagnosed on the basis of clinical examination (Blood pressure of140/90 mm Hg or higher) and laboratory investigation. (Protein urea +1). Blood pressure monitoring was done on every 15 days until the use of medicine.

Category

Treatment - Drugs

2

Description
Control group:. The control group was prescribed placebo in the form a another vitamin supplementation not containing vitamin D. All patients were advised to take medicine (placebo or vitamin D) till 36 weeks of gestation. Preeclampsia was diagnosed on the basis of clinical examination (Blood pressure of140/90 mm Hg or higher) and laboratory investigation. (Protein urea +1). Blood pressure monitoring was done on every 15 days until the use of medicine.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
outpatient department of gynecology department

Full name of responsible person
Dr. Saima

Street address
Nishtar Hospital, Multan

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Multan

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66000

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+92 312 8443876

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saimashahzad35177@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
DME of Nishtar hospital

Full name of responsible person
department of medical education

Street address
Nishtar hospital, Multan

City
Multan

Postal code
66000

Phone
+92 61 4702121

Email
nmu@edu.pk

Grant name

Grant code / Reference number

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

Title of funding source
DME of Nishtar hospital

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
DME, Nishtar hospital Multan

Full name of responsible person
Dr. Saima

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Nishtar Medical University

Full name of responsible person
Saima Shahzad

Position
Assistant Professor

Latest degree
Medical doctor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

due to cultural reasons, patients usually hide personal data on individual basis

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Clinical study types, desgin, and data stats

When the data will become available and for how long

till the end of 2023, for lifelong

To whom data/document is available

all public

Under which criteria data/document could be used

only for citations

From where data/document is obtainable

google scholar and personal email

What processes are involved for a request to access data/document

request on personal email

Comments