

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the Impact of Vitamin D Supplementation with Placebo on Preeclampsia 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

Country

Pakistan

Phone

+92 300 7195857

Email address

saimashahzad35177@gmail.com

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

stratified 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 of 140/90 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 of 140/90 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

City

Multan

Postal code

66000

Phone

+92 312 8443876

Email

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

Street address

Nishtar hospital, Multan

City

Multan

Province

Punjab

Postal code

66000

Phone

+92 311 8443876

Email

saimashahzad35177@gmail.com

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

Gynecology and Obstetrics

Street address

Nishtar hospital, Multan

City

Multan

Province

Punjab

Postal code

66000

Phone

+92 300 7195857

Fax

Email

saimashahzad35177@gmail.com

Person responsible for updating data

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

Gynecology and Obstetrics

Street address

Nishtar hospital, Multan

City

Multan

Province

Punjab

Postal code

66000

Phone

+92 300 7195857

Fax

Email

saimashahzad35177@gmail.com

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, design, 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