

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of calcium and vitamin D co-supplementation on pre-eclampsia parameters, metabolic status and biomarkers of oxidative stress in pregnant women at risk for pre-eclampsia

Protocol summary

Study aim

This study is to determine the effects of vitamin D on metabolic profiles, hs-CRP and biomarkers of oxidative stress in pregnant women at risk for pre-eclampsia.

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct

Sixty pregnant women of eligible and referred to Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primigravida pregnant women; aged 18–40 years old; at risk for pre-eclampsia; lived approximately 20 km or less from the clinic and hospital. Exclusion criteria: Hypertension; renal diseases; gestational diabetes mellitus (GDM); abnormal foetal anomaly scan

Intervention groups

Patients will be assigned to receive either 50000 IU vitamin D/each 2 weeks and 1000 mg calcium daily (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

Pre-eclampsia rate, low birth weight (LBW) (<2500 g), newborn's birth size and preterm delivery (<37 weeks) (primary outcomes) and other metabolic profiles (secondary outcome).

General information

Reason for update

Due to an error, the request for an update in our website has conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201102135444N3**

Registration date: **2015-01-31, 1393/11/11**

Registration timing: **retrospective**

Last update: **2021-05-27, 1400/03/06**

Update count: **1**

Registration date

2015-01-31, 1393/11/11

Registrant information

Name

Mansoor Samimi

Name of organization / entity

Kashan

Country

Iran (Islamic Republic of)

Phone

+98 36 1446 0180

Email address

samimi_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2014-09-06, 1393/06/15

Expected recruitment end date

2014-10-06, 1393/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of calcium and vitamin D co-supplementation on pre-eclampsia parameters, metabolic status and biomarkers of oxidative stress in pregnant women at risk for pre-eclampsia

Public title

Effect of supplementation in treatment of pregnancy complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primigravida pregnant women Aged 18–40 years old At risk for pre-eclampsia Lived approximately 20 km or less from the clinic and hospital

Exclusion criteria:

Hypertension Renal diseases Gestational diabetes mellitus (GDM) Abnormal foetal anomaly scan

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Clinic who is not involved in the trial and not aware of random sequences will be allocated the numbered bottles of capsules to participants. Supplements and placebo are in the same packaging at the pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 60 by a random number generator (<https://stattrek.com/statistics/random-number-generator.aspx>) and patients will be randomly assigned into each intervention group by their numbers.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2014-03-31, 1393/01/11

Ethics committee reference number

196/1/5/29/پ

Health conditions studied

1

Description of health condition studied

Pre-eclampsia

ICD-10 code

O94

ICD-10 code description

Sequelae of complication of pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Pre-eclampsia rate

Timepoint

After delivery

Method of measurement

Medical record

2

Description

Low birth weight (LBW) (<2500 g)

Timepoint

After delivery

Method of measurement

Scale

3

Description

Newborn's birth size

Timepoint

After delivery
Method of measurement
Scale and tape

4

Description
Preterm delivery (<37 weeks)
Timepoint
After delivery
Method of measurement
Medical record

Secondary outcomes

1

Description
Insulin
Timepoint
Baseline and End-of-trial
Method of measurement
Eliza

2

Description
Nitric oxide
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

3

Description
High-sensitivity C-reactive protein
Timepoint
Baseline and End-of-trial
Method of measurement
Eliza

4

Description
Total antioxidant capacity
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

5

Description
Fasting plasma glucose
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic

6

Description

Triglyceride
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic

7

Description
Cholesterol
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic

8

Description
HDL-cholesterol
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic

9

Description
Blood pressures
Timepoint
Baseline and End-of-trial
Method of measurement
Manometer

Intervention groups

1

Description
Intervention group: 50000 IU vitamin D pearl, each two weeks for 12 weeks + 1000 mg calcium tablet, daily for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Vitamin D Placebo pearl, each two weeks for 12 weeks + Calcium Placebo tablet, daily for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gynecology Clinic
Full name of responsible person
Dr Mansooreh Samimi

Street address
Shahid Rajaee Street, Kashan
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dr_samimi.2007@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Dr Gholamali Hamidi
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hamidi_g@kaums.ac.ir

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, Kashan University of Medical Sciences

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
Kashan University of Medical Sciences
Full name of responsible person

Dr Mansooreh Samimi
Position
Obstetricians
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Fax**Email**

dr_samimi.2007@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available