Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Effects of calcium and vitamin D co-supplementation on pre-elampsia 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
Mansoore Samimi

Name of organization / entity
Kashan

Country
Iran (Islamic Republic of)

Phone
+98 36 1446 0180

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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-elampsia 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
Isfehan

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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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
Street address
Vice chancellor for research, Ghotbe Ravandi Boulevard
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+98 31 5554 0021
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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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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