

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effects of vitamin D supplementation on metabolic profiles in pregnant women who are at risk of pre-eclampsia

Protocol summary

Study aim

Objective: 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

Population and sample size: 60 pregnant women of eligible and referred to Taleghani and Emam Reza Clinics affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women primigravida and aged 18 to 40 years and at risk for pre-eclampsia will be included in this study. Exclusion criteria: Unable or unwilling to give written informed consent, Abnormal fetal anomaly scan and treated with warfarin

Intervention groups

Patients will be assigned to receive either 50000 IU vitamin D/each 2 weeks (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

Acronym

IRCT registration information

IRCT registration number: **IRCT201410035623N27**

Registration date: **2014-10-04, 1393/07/12**

Registration timing: **retrospective**

Last update: **2019-09-16, 1398/06/25**

Update count: **1**

Registration date

2014-10-04, 1393/07/12

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of vitamin D supplementation on metabolic profiles in pregnant women who are at risk of pre-eclampsia

Public title

Effect of supplementation in treatment of pregnancy complications

Purpose

Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women primigravida Aged 18-40 years old At risk for pre-eclampsia
Exclusion criteria:
Unable or unwilling to give written informed consent
Abnormal fetal anomaly scan Treated with warfarin
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either vitamin D supplements (n=30) or placebo (n=30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at gynecology clinic affiliated to Arak University of Medical Sciences, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Vice-chancellor for Education and Research, Sardasht Avenue, Arak

City

Arak
Province
Markazi
Postal code
3819693345

Approval date

2013-08-26, 1392/06/04

Ethics committee reference number

92/151/2

Health conditions studied

1

Description of health condition studied

Pregnancy

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

hs-CRP

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: Vitamin D pearl, 50000 IU, each two weeks for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo pearl, each two weeks for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Taleghani and Emam Reza Clinics

Full name of responsible person

Maryam Karamali

Street address

Arak, Emam Khomaini Street, Taleghani Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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