

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1534 3570

###### Email address

asemi\_z@kaums.ac.ir

##### 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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**Email**

dr.karamali@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Maryam Karamali

**Street address**

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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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**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