

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Effect of different doses of vitamin D on insulin resistance in pregnant women attending in Shahid Sadoughi and Mojobian prenatal clinics

#### Protocol summary

##### Summary

The objective of this randomized, not blinded trial is to investigate the effect of different doses of vit D on the insulin resistance in pregnant women. In this study, 90 pregnant women who meet the inclusion/exclusion criteria will be recruited and randomly assigned into two interventions or control group. The pregnant women in the intervention groups will receive 2000 or 4000 IU vit D daily for 6 months while in the control group will receive 200 IU (conventional dose) vit D, daily for 6 months. Fasting blood sugar, 25 hydroxy vit D, insulin and homeostatic model assessment (HOMA) will be measured before and after the intervention and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138811203312N1**  
Registration date: **2011-05-23, 1390/03/02**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-05-23, 1390/03/02

##### Registrant information

##### Name

Sedigheh Soheilykhah

##### Name of organization / entity

Yazd Diabetes Research Center, Shahid Sadoughi  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1522 3999

##### Email address

s\_soheilykhah@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Yazd Diabetes Research Center, Shahid Sadoughi  
University of Medical Sciences

##### Expected recruitment start date

2010-03-06, 1388/12/15

##### Expected recruitment end date

2011-09-06, 1390/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of different doses of vitamin D on insulin  
resistance in pregnant women attending in Shahid  
Sadoughi and Mojobian prenatal clinics

##### Public title

Effect of different doses of vitamin D on insulin  
resistance in pregnant women attending in Shahid  
Sadoughi and Mojobian prenatal clinics

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: pregnant women with gestational age  
less than 12 weeks without gestational diabetes, history  
of PCO, BMI less than 27kg/m<sup>2</sup> before pregnancy, no Vit  
D supplementation in the past 6 months Exclusion  
criteria: diabetes or gestational diabetes treated with  
insulin, thyroid or parathyroid disorders, hypertension,  
polycystic ovary (PCO) s

##### Age

No age limit

##### Gender

Female

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 90

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Yazd Diabetes Research Center, Shahid Sadoughi  
University of Medical Sciences

##### Street address

Afshar Alley, Jomhuri BLV. , Yazd, Iran

##### City

Yazd

##### Postal code

8917965556

##### Approval date

2010-08-08, 1389/05/17

##### Ethics committee reference number

48204/17/پ

## Health conditions studied

### 1

#### Description of health condition studied

Gestational Diabetes

#### ICD-10 code

O24

#### ICD-10 code description

Diabetes mellitus in pregnancy

## Primary outcomes

### 1

#### Description

Insulin

#### Timepoint

Before intervention and 6 months after intervention

### Method of measurement

Insulin kit

### 2

#### Description

Vitamin D

#### Timepoint

Before intervention and 6 months after intervention

#### Method of measurement

Vit D kit

### 3

#### Description

FBS

#### Timepoint

Before intervention and 6 months after intervention

#### Method of measurement

Auto Analyser method

### 4

#### Description

Insulin resistance Index

#### Timepoint

Before intervention and 6 months after intervention

#### Method of measurement

Measuring of HOMA index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1: Vit D supplementation, 2000 IU,  
daily for 6 months

#### Category

Treatment - Drugs

### 2

#### Description

Control group: vit D, 200 IU (conventional dose), daily for  
6 months

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group2: Vit D supplementation, 4000 IU,  
daily for 6 months

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Shahid Sadoughi and Mojibian prenatal clinics in Yazd

**Full name of responsible person**

Dr. Sedigheh Soheilykhah

**Street address**

Shahid Sadoughi hospital, Yazd, Iran

**City**

Yazd

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Yazd Diabetes Research Center, Shahid Sadoughi  
University of Medical Sciences

**Full name of responsible person**

Dr. Sedigheh Soheilykhah

**Street address**

Afshar Alley, Jomhuri BLV. , Yazd, Iran

**City**

Yazd

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

Yes

**Title of funding source**

Yazd Diabetes Research Center, Shahid Sadoughi  
University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Yazd Diabetes Research Center, Shahid Sadoughi  
University of Medical Sciences

**Full name of responsible person**

Dr. Sedigheh Soheilykhah

**Position**

Assistant professor of internal medicine

**Other areas of specialty/work****Street address**

Afshar Alley, Jomhuri BLV. , Yazd, Iran

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s\_soheilykhah@ssu.ac.ir

**Web page address**

### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Yazd Diabetes Research Center, Shahid Sadoughi  
University of Medical Sciences

**Full name of responsible person**

Dr. Sedigheh Soheilykhah

**Position**

Assistant professor of internal medicine

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### Person responsible for updating data

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*