

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A clinical trial to investigate the effect of vitamin D supplementation on glucose status in mothers with gestational diabetes

#### Protocol summary

##### Summary

The main objective of this study is determining the effect of vitamin D supplementation on glucose status in mothers with gestational diabetes. This investigation is a randomized controlled clinical trial on 40 pregnant women with gestational diabetes in first trimester who are admitted in gynecology clinic in Kerman. Inclusion criteria: women over 18 year-old and gestational age of 18 to 13 week. Exclusion criteria: kidney or hepatic failure; alcoholism; malabsorption; hypo or hyperparathyroidism; malignancies; consumption of drugs affecting vitamin D metabolism; using vitamin D supplements; history of diabetes. Glucose Tolerance Test (GTT) is done by injecting 75 gr Glucose and patients with abnormal results are divided into two groups using simple randomization. Both groups will have nutritional regimen. Beside this regimen, in intervention group oral vitamin D (50000 IU) is given every two weeks for three doses and control group does not receive any supplemental vitamin D. During this period, patients who need insulin will be excluded. Two weeks following the last dose of vitamin D, FBS, fasting insulin and HbA1c level will be measured and HOMA-IR is calculated. Also the patients will be observed for gestational problems including intrauterine fetal death (IUFD), Intrauterine growth restriction (IUGR), Large for gestational age (LGA), preeclampsia, premature birth, abortion and requirement for insulin regimen until the end of pregnancy. After labour, a sample of umbilical cord is taken for measuring vitamin D level and the association of it with gestational problems will be determined.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015122725725N1**

Registration date: **2016-01-08, 1394/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-01-08, 1394/10/18

##### Registrant information

###### Name

Tayebeh Naderi

###### Name of organization / entity

Kerman University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3322 2250

###### Email address

t\_naderi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kerman University of Medical Sciences

##### Expected recruitment start date

2015-03-21, 1394/01/01

##### Expected recruitment end date

2015-09-23, 1394/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial to investigate the effect of vitamin D supplementation on glucose status in mothers with gestational diabetes

##### Public title

Effect of vitamin D supplementation on controlling blood sugar in patients with gestational diabetes

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: women over 18 year-old; gestational age of 18 to 13 week. Exclusion criteria: kidney or hepatic failure; alcoholism; malabsorption; hypo or hyperparathyroidism; malignancies; consumption of drugs affecting vitamin D metabolism; using vitamin D supplements; history of diabetes.

### **Age**

From **17 years** old to **60 years** old

### **Gender**

Female

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **40**

### **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**

The ethics committee of Kerman University of Medical sciences

##### **Street address**

Shafa Square

##### **City**

Kerman

##### **Postal code**

##### **Approval date**

2015-10-27, 1394/08/05

##### **Ethics committee reference number**

IR.KMU.REC.1394.203

## **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**

HbA1c level

#### **Timepoint**

two weeks after the last dose of Vitamin D

#### **Method of measurement**

BLOOD TEST

### 2

#### **Description**

FBS (fasting blood sugar)

#### **Timepoint**

two weeks after the last dose of Vitamin D

#### **Method of measurement**

BLOOD TEST

### 3

#### **Description**

INSULIN LEVEL IN BLOOD

#### **Timepoint**

two weeks after the last dose of Vitamin D

#### **Method of measurement**

BLOOD TEST

### 4

#### **Description**

Insulin resistance

#### **Timepoint**

two weeks after the last dose of Vitamin D

#### **Method of measurement**

Homeostasis model assessment (HOMA-IR)

## **Secondary outcomes**

### 1

#### **Description**

IUFD (intrauterine fetal death)

#### **Timepoint**

during pregnancy

#### **Method of measurement**

sonography

### 2

#### **Description**

IUGR (Intrauterine growth restriction)

#### **Timepoint**

during pregnancy

#### **Method of measurement**

sonography

### **3**

#### **Description**

LGA (Large for gestational age)

#### **Timepoint**

during pregnancy

#### **Method of measurement**

sonography

### **4**

#### **Description**

preeclampsia

#### **Timepoint**

during pregnancy

#### **Method of measurement**

Examination

### **5**

#### **Description**

premature birth

#### **Timepoint**

during pregnancy

#### **Method of measurement**

Examination

### **6**

#### **Description**

vitamin D level of umbilical cord

#### **Timepoint**

after birth

#### **Method of measurement**

Diazon kit

## **Intervention groups**

### **1**

#### **Description**

In intervention group: oral vitamin D (50000 IU) every two weeks is given for three doses

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

control group: they do not receive any supplemental vitamin D

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Afzalipoor Hospital

##### **Full name of responsible person**

Sonia Ahmadi

#### **Street address**

Afzalipoor Hospital, Zendan Square

#### **City**

Kerman

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research, Kerman University of Medical Sciences

##### **Full name of responsible person**

Fatemeh Hassani

##### **Street address**

Tahmasbabad Square, Ebnesina Street

##### **City**

Kerman

#### **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, Kerman 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**

Kerman University of Medical Sciences

##### **Full name of responsible person**

TAYEBEH NADERI

##### **Position**

gynecologist

##### **Other areas of specialty/work**

##### **Street address**

Afzalipoor Hospital, Zendan Square

##### **City**

KERMAN

##### **Postal code**

##### **Phone**

+998 3432235011

##### **Fax**

##### **Email**

t\_NADERI@KMU.AC.IR

##### **Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Mohadess Peydayesh

**Position**

Assistant of gynecology

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

Afzalipoor Hospital, Zendan Square

**City**

Kerman

**Postal code****Phone**

+98 34 3223 5011

**Fax****Email**

mohades.peydayesh@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Mohadess Peydayesh

**Position**

Assistant of gynecology

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

Afzalipoor Hospital, Zendan Square

**City**

Kerman

**Postal code****Phone**

+98 34 3223 5011

**Fax****Email**

mohades.peydayesh@yahoo.com

**Web page address**

## 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*