

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effect of concomitant administration of vaginal progesterone and vitamin D3 in the treatment of unexplained recurrent abortion in pregnant women

#### Protocol summary

##### Summary

The purpose of this double-blinded clinical trial is to determine the effect of concomitant administration of vaginal progesterone and vitamin D3 in the treatment of unexplained recurrent abortion in pregnant women referring to Shabih Khani Hospital in Kashan. In this study, all women with history of recurrent abortions of unknown causes are entered into the study after obtaining informed consent. After performing a complete history and physical exam, the patients' demographic data and obstetric history are obtained using a questionnaire. After performing complete lab tests including Anticardiolipin, TSH, PT, PTT, INR, B2GP, factor v leiden, protein s and c, prolactin, and Lupus anticoagulants; the parents' karyotype to rule out chromosomal disorders; Hysterosalpingography to rule out uterine anomalies and applying the inclusion and exclusion criteria; 80 patients are selected and divided into two groups of 40 with block sizes of 4 and 6. In the first group vaginal progesterone is administered alone at a dose of 400 mg daily and the second group is treated with the same dose of vaginal progesterone and vitamin D pearls at a dose of 4000 IU daily. Both groups will also receive standard supplements such as iron and folic acid. All patients will be followed until the 20th week of pregnancy. At the end of the 20th week, occurrence or non-occurrence of abortion and the levels of inflammatory factors such as IL17 will be evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013100114853N1**

Registration date: **2013-10-30, 1392/08/08**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-10-30, 1392/08/08

##### Registrant information

###### Name

Farzaneh Amini

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1555 0021

###### Email address

amini-si@kaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for research, Kashan University of Medical Sciences

##### Expected recruitment start date

2013-11-22, 1392/09/01

##### Expected recruitment end date

2014-01-21, 1392/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of concomitant administration of vaginal progesterone and vitamin D3 in the treatment of unexplained recurrent abortion in pregnant women

##### Public title

The impact of vaginal progesterone and vitamin D3 on the treatment of unexplained recurrent abortion

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Incidence of 3 or more consecutive recurrent abortions or 2 or more non consecutive abortions; Age less than 35 years and above 18 years; The absence of any known causes of abortion; Pregnancies from one single husband in previous and current abortions Exclusion criteria: Uterine anomalies; The history of allergy on the consumption of progesterone and multivitamins containing vitamin D3; initial abnormal tests of thyroid abnormalities, prolactin, antiphospholipid antibody syndrome and thrombophilia

### **Age**

From **18 years** old to **35 years** old

### **Gender**

Female

### **Phase**

N/A

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

*No information*

### **Sample size**

Target sample size: **80**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Kashan University of Medical Sciences ethics committee

##### **Street address**

Pezeshk Blvd., Ghotb Ravandi Blvd., Kashan Medical Sciences complex, Vice chancellor for research

##### **City**

Kashan

##### **Postal code**

88141/87159

#### **Approval date**

2013-08-26, 1392/06/04

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

P/29/5/1/2059

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Recurrent abortion

#### **ICD-10 code**

O03

#### **ICD-10 code description**

spontaneous abortion

## **Primary outcomes**

### **1**

#### **Description**

continuation of pregnancy beyond 20 weeks of pregnancy in women with recurrent abortion

#### **Timepoint**

20 weeks after the first day of last menstrual period

#### **Method of measurement**

clinical, laboratory and sonographic findings

## **Secondary outcomes**

### **1**

#### **Description**

continuation of pregnancy

#### **Timepoint**

after pregnancy termination

#### **Method of measurement**

after pregnancy termination

## **Intervention groups**

### **1**

#### **Description**

control group: Participants are treated with 400 mg vaginal progesterone suppositories (manufactured by Behvazan Pharmaceutical company, Iran) at a dose of 400 mg/day until the 20th week of pregnancy.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

control group: Participants are treated with vaginal progesterone suppositories at a dose of 400 mg/day manufactured by Behvazan Pharmaceutical company, Iran, and vitamin D3 at a dose of 4000 IU/day (slow-release tablets of vitamin D manufactured by Dana Pharmaceutical company).

#### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Shabih Khani Hospital of Kashan

**Full name of responsible person**

Farzaneh Amini

**Street address**

Shabih Khani Maternity Hospital, Shahid Beheshti Street, Ayatollah Kashani Crossroad

**City**

Kashan

Street, Ayatollah Kashani Crossroad

**City**

Kashan

**Postal code**

8714715555

**Phone**

+98 36 1446 0180

**Fax****Email**

amini-si@kaums.ac.ir

**Web page address**

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Vice Chancellor for research, Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Gholam Ali Hamidi

**Street address**

Vice Chancellor for research, Kashan University of Medical Sciences complex, Pezeshk Blvd., Ghotbe Ravandi Blvd.

**City**

Kashan

**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**

*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**

Department of Obstetrics and Gynecology, Kashan Medical School

**Full name of responsible person**

Farzaneh Amini

**Position**

Resident of ob & gyn/ MD

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

Shabih Khani Maternity Hospital, Shahid Beheshti

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Farzaneh Amini

**Position**

Resident of ob & gyn/ MD

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

Shabih Khani Maternity Hospital, Shahid Beheshti Street, Ayatollah Kashani Crossroad

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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*