

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

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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**

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Full name of responsible person

Farzaneh Amini

Position

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

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Person responsible for updating data

Contact**Name of organization / entity**

Department of Obstetrics and Gynecology, Kashan Medical School

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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