

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Assessing the effect of adding vitamin D and vitamin E to metformin with dydrogesterone regimen in the treatment of infertile women with polycystic ovary syndrome

Protocol summary

Summary

The aim of this study is assessing the effect of vitamin E and vitamin D in metformin with dydrogesterone regimen in the treatment of infertile women with polycystic ovary syndrome (PCOS). This assessing is done by studying menstrual discipline, follicle maturation, endometrial thickness and the pregnancy occurrence in infertile women with PCOS. PCOS patients are identified by Rotterdam criteria and are randomly divided into two groups. In one group vitamin D and in the other group vitamin E level will be measured. Patients will be divided again in to 4 categories based on vitamin E and vitamin D level (vitamin D deficient, vitamin D sufficient, vitamin E deficient, vitamin E sufficient). These four groups will be divided into two groups as case and control. Metformin with dydrogesterone regimen will be considered as the basement of therapy in all groups. Vitamin D will be added to the cases of the first group and vitamin E will be added to the cases of the second one as adjuvant therapy. Patients will take drugs for three months and the conclusion will be done on the base of the additive effect of therapy, assessing changes in the menstrual state, the sonographic evaluation, success in pregnancy and weight changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022821653N5**

Registration date: **2016-10-25, 1395/08/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-25, 1395/08/04

Registrant information

Name

Athar Rasekh Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 5432 6602

Email address

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Recruitment status

Recruitment complete

Funding source

Jahrom University of Medical Science

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of adding vitamin D and vitamin E to metformin with dydrogesterone regimen in the treatment of infertile women with polycystic ovary syndrome

Public title

The influence of vitamin D and vitamin E in the treatment of infertile women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women with polycystic ovary syndrome (PCOS): which had no pregnancy history after 12 months of unprotected intercourse. Exclusion criteria: Women with other causes of infertility such as endometriosis: internal and surgical diseases: and patients who do not have polycystic ovary syndrome (PCOS) criteria.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **317**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Table of random numbers for choosing patients

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Jahrom University of Medical Science

Street address

Jahrom University of Medical Science. Motahari boulevard

City

Jahrom

Postal code**Approval date**

2016-02-05, 1394/11/16

Ethics committee reference number

IR.JUMS.REC.1394.177

Health conditions studied**1****Description of health condition studied**

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovary syndrome

Primary outcomes**1****Description**

Follicle size

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Sonography

2**Description**

Endometrial thickness

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Sonography

3**Description**

Menstrual discipline

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Sonography

4**Description**

Pregnancy

Timepoint

Before intervention and 3 months after intervention

Method of measurement

BHCG

5**Description**

Weight

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Scale

Secondary outcomes

empty

Intervention groups**1****Description**

intervention group 3: metformin 500mg by Shafa pharmaceuticals: one tablet daily for the first week: two

tablets daily for the second week and then three tablets daily from the third week to the rest of therapy for three months. tablet Dydrogesterone 10mg by solvay pharmaceuticals one tablet daily from the fifteenth day of menstrual cycle to the twenty fifth day of it for three months. tablet vitamin E 400mg from Dana pharmaceuticals one tablet daily for three months. control group 3: only metformin 500mg by Shafa pharmaceuticals: one tablet daily for the first week: two tablets daily for the second week and then three tablets daily from the third week to the rest of therapy for three months. tablet Dydrogesterone 10mg by solvay pharmaceuticals one tablet daily from the fifteenth day of menstrual cycle to the twenty fifth day of it for three months.

Category

Treatment - Drugs

2

Description

intervention group 2: metformin 500mg by Shafa pharmaceuticals: one tablet daily for the first week: two tablets daily for the second week and then three tablets daily from the third week to the rest of therapy for three months. tablet Dydrogesterone 10mg by solvay pharmaceuticals one tablet daily from the fifteenth day of menstrual cycle to the twenty fifth day of it for three months. capsule vitamin D1000IU from Zahravay pharmaceuticals one capsule daily for three months. control group 2: only metformin 500mg by Shafa pharmaceuticals: one tablet daily for the first week: two tablets daily for the second week and then three tablets daily from the third week to the rest of therapy for three months. tablet Dydrogesterone 10mg by solvay pharmaceuticals one tablet daily from the fifteenth day of menstrual cycle to the twenty fifth day of it for three months.

Category

Treatment - Drugs

3

Description

intervention group 1: metformin 500mg by Shafa pharmaceuticals: one tablet daily for the first week: two tablets daily for the second week and then three tablets daily from the third week to the rest of therapy for three months. tablet Dydrogesterone 10mg by solvay pharmaceuticals one tablet daily from the fifteenth day of menstrual cycle to the twenty fifth day of it for three months. capsule vitamin D1000IU from Zahravay pharmaceuticals one capsule daily for three months. control group 1: only metformin 500mg by Shafa pharmaceuticals: one tablet daily for the first week: two tablets daily for the second week and then three tablets daily from the third week to the rest of therapy for three months. tablet Dydrogesterone 10mg by solvay pharmaceuticals one tablet daily from the fifteenth day of menstrual cycle to the twenty fifth day of it for three months.

Category

Treatment - Drugs

4

Description

intervention group4: metformin 500mg by Shafa pharmaceuticals: one tablet daily for the first week: two tablets daily for the second week and then three tablets daily from the third week to the rest of therapy for three months. tablet Dydrogesterone 10mg by solvay pharmaceuticals one tablet daily from the fifteenth day of menstrual cycle to the twenty fifth day of it for three months. tablet vitamin E 400mg from Dana pharmaceuticals one tablet daily for three months. control group 4: only metformin 500mg by Shafa pharmaceuticals: one tablet daily for the first week: two tablets daily for the second week and then three tablets daily from the third week to the rest of therapy for three months. tablet Dydrogesterone 10mg by solvay pharmaceuticals one tablet daily from the fifteenth day of menstrual cycle to the twenty fifth day of it for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Rasekh Jahromi Infertility Clinic

Full name of responsible person

Athar Rasekh Jahromi

Street address

22 Bahman Avenue

City

Jahrom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of jahrom university of medical science

Full name of responsible person

Dr Kavous Solhjo

Street address

Jahrom University of Medical Science, Motahari boulevard

City

Jahrom

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 of jahrom university of medical science

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

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Jahrom University of Medical Science

Full name of responsible person

Dr Kavous Solhjo

Position

Phd of microbiology, Vice Chancellor for research of jahrom university od medical science

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Full name of responsible person

Fatemeh Kargarfard

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medical student

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Position

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City

Jahrom

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