Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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
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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 Sience
Street address
Jahrom University of Medical Sience. 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
Menstural 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 menstural cycle to the twenty fifth day of it for three months. capsule vitamin D1000IU from Zahravy 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 menstural 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 Zahravy 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 sience

Full name of responsible person

Dr Kavous Solhjo

Street address

Jahrom University of Medical Sience, 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 sience

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
Jahrom University of Medical Sience
Full name of responsible person
Dr Kavous Solhjo
Position
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Person responsible for scientific inquiries

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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