Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of portulaca oleracea L. and foeniculum vulgare mill and vitex agnus castus L. with spironolactone and cyproterone compound on hirsutism on patient with polycystic ovary syndrome

Protocol summary

Summary

The purpose of this study is Comparison of the effect of portulaca oleracea L. and foeniculum vulgare mill and vitex agnus castus L. with spironolactone and cyproterone compound on hirsutism on patient with polycystic ovary syndrome inclusion criteria : in the age range of 18 to 40 years of age ; absence of chronic physical illness (other than polycystic ovary syndrome) Exclusion criteria : history of specific drug use (effects on levels of hormones, blood glucose, insulin or hirsutism); previous history of diabetes, cardiovascular disease, thyroid disease . This randomized study was performed on 128 polycystic ovary syndrome women. These patients will be randomly divided into control and test groups . The control group will receive spironolactone and cyproterone compound , and the group will receive the portulaca oleracea L. and foeniculum vulgare mill and vitex agnus castus L. The treatment is performed for six months, then based on the Ferriman-Gallway scoring system on hirsutism that evaluates the extent of hair growth in most sensitive areas of the hair and tests including FSH, LH, PRL, and DHEAS in the test and control group It takes place.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062121653N7**
Registration date: **2017-10-01, 1396/07/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-10-01, 1396/07/09

Registrant information

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Name of organization / entity
Jahrom University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Jahrom University of Medical Sciences

Expected recruitment start date

2018-01-01, 1396/10/11

Expected recruitment end date

2019-12-30, 1398/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of portulaca oleracea L. and foeniculum vulgare mill and vitex agnus castus L. with spironolactone and cyproterone compound on hirsutism on patient with polycystic ovary syndrome

Public title

Comparison of the effect of portulaca oleracea L. and foeniculum vulgare mill and vitex agnus castus L. with spironolactone and cyproterone compound on hirsutism on patient with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria :oral and written judgment for participation in the study; in the age range of 18 to 40 years of age ; absence of chronic physical illness (other than polycystic ovary syndrome), and mental illness or drug use In the long time, it has been the patient's own words. Exclusion criteria : history of specific drug use (effects on levels of hormones, blood glucose, insulin or hirsutism); previous history of diabetes, cardiovascular disease, thyroid disease ; other surgical and internal diseases. They do not have PCOS cryptography.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **128**

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

Jahrom University of Medical Sciences

Street address

Jahrom, Motahari Blvd. pardis building

City

jahrom

Postal code

Approval date

2017-07-29, 1396/05/07

Ethics committee reference number

IR.JUMS.REC.1395.169

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

hirsutism

Timepoint

3 month

Method of measurement

Ferriman-Gallway Scoring system

Secondary outcomes

1

Description

free testosterone

Timepoint

3month

Method of measurement

mg/ml

2

Description

follicle-stimulating hormone

Timepoint

3 month

Method of measurement

mg/ml

3

Description

Luteinizing Hormone

Timepoint

3 month

Method of measurement

mg/ml

Intervention groups

1

Description

The herbal diet intervention group contains 6 capsules per 24 hours, each dose of each capsule is 550 mg, and each capsule contains 25% portulaca oleracea L.(137 mg) + 25% foeniculum vulgare mill (137 mg) + 50% vitex agnus castus L.(275 mg). The treatment is for 3 months.

Category

Treatment - Drugs

2

Description

To the control group, the spironolactone (one daily dose of 100 mg) and cyproterone compound (one tablet daily dose of 50 mg) are given

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Peimanieh hospital

Full name of responsible person

Dr Athar Rasekh Jahromi

Street address

Peimanieh hospital, Valiasr street,Jahrom

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research ,Jahrom University of Medical Sciences

Full name of responsible person

Ramezani

Street address

Pardis, The end of Bulvar Professor Motahari, Jahrom .

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 ,Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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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