

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Clinical comparison of the effects of *Foeniculum vulgare* fruit and medroxyprogesterone in treatment of abnormal uterine bleedings in patients with polycystic ovarian syndrome

Protocol summary

Summary

The aim of this study is the comparison of clinical efficacy of fennel fruit and medroxyprogesterone in treatment of abnormal uterine bleedings in patients with polycystic ovarian syndrome. The study is randomized, not blinded, without a placebo control and in 1-2 trial phase. The main objective of study is treatment and from the type of intervention. The inclusion criteria include having polycystic ovary syndrome and menstrual disorders and the exclusion criteria is non-compliance to the plan. The number of patients is 66 that 33 patients receive fennel and 33 patients take medroxyprogesterone. The intervention period is 3 months and the primary outcomes of the study include oligomenorrhea, hypermenorrhea, menorrhagia, polymenorrhea, menometrorrhagia, metrorrhagia and amenorrhea.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903013922N2**

Registration date: **2015-02-04, 1393/11/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-04, 1393/11/15

Registrant information

Name

Masoud Modarresi

Name of organization / entity

Faculty of Pharmacy - Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1835 6168

Email address

mmodarresi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2014-12-01, 1393/09/10

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical comparison of the effects of *Foeniculum vulgare* fruit and medroxyprogesterone in treatment of abnormal uterine bleedings in patients with polycystic ovarian syndrome

Public title

The effect of fennel fruit in treatment of abnormal uterine bleedings caused by polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: polycystic ovarian syndrome; abnormal uterine bleeding. Exclusion criteria: non-compliance to the plan.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 66

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**

Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Building
No. 2, Shaheed Beheshti Blv., Kermanshah

City

Kermanshah

Postal code**Approval date**

2014-08-16, 1393/05/25

Ethics committee reference number

20359

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

Polycystic Ovarian Syndrom

ICD-10 code

E28.2

ICD-10 code description

Sclerocystic ovary syndrome

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

oligomenorrhea

Timepoint

the first day of the study, 90th day

Method of measurement

questionnaire

2**Description**

hypermenorrhea

Timepoint

the first day of the study, 90th day

Method of measurement

questionnaire

3**Description**

menorrhagia

Timepoint

the first day of the study, 90th day

Method of measurement

questionnaire

4**Description**

polymenorrhagia

Timepoint

the first day of the study, 90th day

Method of measurement

questionnaire

5**Description**

menometrorrhagia

Timepoint

the first day of the study, 90th day

Method of measurement

questionnaire

6**Description**

metrorrhagia

Timepoint

the first day of the study, 90th day

Method of measurement

questionnaire

7**Description**

amenorrhea

Timepoint

the first day of the study, 90th day

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group, aqueous extract of fennel fruit (capsule form) is given orally, 600 mg twice in a day for three consecutive months.

Category

Treatment - Drugs

2

Description

In control group, medroxyprogesterone is given orally, 5 mg twice in a day for 10 consecutive days during three consecutive menstrual cycles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private Clinic of Gynecologist

Full name of responsible person

Dr. Nasrin Jalilian

Street address

Shafa Building, Shahrdari Parking, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Kermanshah University of Medical Sciences, Building No. 2, Shaheed Beheshti Blv., Kermanshah

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of medical Sciences, Faculty of Pharmacy

Full name of responsible person

Dr. Masoud Modarresi

Position

Member of the Scientific Board of the University / Associate Professor (Ph.D.)

Other areas of specialty/work

Street address

Faculty of Pharmacy, Parastar Blv., Dnashgah St., Shaheed Shiroodi Blv.

City

Kermanshah

Postal code

6734667149

Phone

+98 83 3427 6482

Fax

Email

mmodarresi@kums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of medical Sciences, Faculty of Pharmacy

Full name of responsible person

Dr. Masoud Modarresi

Position

Member of the Scientific Board of the University / Assistant Professor (Ph.D.)

Other areas of specialty/work

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of medical Sciences, Faculty of Pharmacy

Full name of responsible person

Dr. Masoud Modarresi

Position

Member of the Scientific Board of the University /
Associate Professor (Ph.D.)

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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