

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Oct 2020

Effect of Ferrula assa foetida and Fennle on improving PCOs women who refer to clinic

Protocol summary

Summary

The aim of the study is to explore the effects of the raw extracts of the herbs asafetida and fennel on polycystic ovary syndrome (PCOS). The study is a triple-blind randomized clinical trial. The study population consists of female students aged 15-30 years who complain of oligomenorrhea and obtain a score of at least 8 on Ferriman-Gallwey questionnaire. The subjects who are not willing to participate in the study, or have used medication over the past three months, or have participated in a similar study are excluded. Materials and methods: 45 of the participants whose hirsutism scores according to Ferriman-Gallwey questionnaire were 8 or above underwent sonography for determination of their ovarian morphology. In addition, blood samples were taken for measurement of their sex hormones. Subsequently, the 45 participants were randomly divided into three groups to receive one of the three interventions of placebo, asafetida and fennel for two months, twice daily. At the end of the interventions, the participants' degrees of hirsutism were re-evaluated using Ferriman-Gallwey questionnaire and the sonography and blood sample collection were repeated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040427207N1**

Registration date: **2016-11-12, 1395/08/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-12, 1395/08/22

Registrant information

Name

Fatemeh Ghavi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71543404059

Email address

fghavi@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Dr Kavous Solhju: Vice Chancellor for Research

Expected recruitment start date

2012-06-30, 1391/04/10

Expected recruitment end date

2015-05-23, 1394/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ferrula assa foetida and Fennle on improving PCOs women who refer to clinic

Public title

Effect of Ferrula assa foetida and Fennle on improving PCOs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: student girls aged 15-30 years were complained of oligo/amenorrhea; hirsutism score ≥ 8 based on Ferriman-Galway scale. Exclusion criteria: history of medical treatment from 3 months age; participation in another study; no willing to participate in

this study.

Age

From **15 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jahrom University of Medical Sciences

Street address

Ostad Motahari Blv

City

Jahrom

Postal code

Approval date

2014-06-18, 1393/03/28

Ethics committee reference number

Jums.REC.1393.023

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

pcos syndrom

Timepoint

befor intervention,third after intervention

Method of measurement

sonography,freriman-galway(f-g scale),hormonal changes

2

Description

improving PCOs symptoms

Timepoint

before the study, 3 month after the study

Method of measurement

Hormonal chnges, sonography parameters, Ferriman-Galway (F-G scale) score

Secondary outcomes

1

Description

Sonographic data

Timepoint

before the intervention, 3 months after the intervention

Method of measurement

Sonography system

2

Description

Hirsotism Score of Freman-Galway

Timepoint

before the intervention

Method of measurement

Questionnaire of Freman_Galway

3

Description

Hormonal changes

Timepoint

before the intervention, 3 months after the intervention

Method of measurement

Elisa Methode

Intervention groups

1

Description

Oral capsules of 100 mg Ferrula assa-foetida for 3 months twice a day

Category

Treatment - Drugs

2

Description

Oral capsules of 100 mg Fennel for 3 months twice a day

Category

Treatment - Drugs

3

Description

Oral capsules of 100 mg placebo for 3 months twice a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Jahrom University of Medical Sciences

Full name of responsible person

Fatemeh Ghavi

Street address

City

Jahrom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom university of medical sciences

Full name of responsible person

Dr Kavous Solhju

Street address

fars, jahrom, jahrom university of medical sciences

City

jahrom

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

fatemeh Ghavi

Position

Instructor of faculty member of nursing and midwifery school

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