Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evalution of the effect of combination therapy with extract of Bunium Persicum and Foeniculum Vulgare on clinical features in Polycystic Ovary Syndrome (PCOS) patients

Protocol summary

Study aim
Determination of the effect of combination therapy with extract of Bunium Persicum and Foeniculum Vulgare on clinical features in Polycystic Ovary Syndrome (PCOS) patients

Design
In this study, 70 patients with PCOS with inclusion criteria are divided into two groups.control and intravention group, the control group receive only the routine treatment plus placebo , and the intervention group receive in addition to routine drugs, the combination with extract of Bunium Persicum and Foeniculum Vulgare twice daily. after four months the therapeutic effects of the capsule will be examined.

Settings and conduct
Clinical trial; Women's Specialty Clinic; placebo-controlled

Participants/Inclusion and exclusion criteria
Inclusion criteria: Polycystic ovary syndrome Exclusion criteria: History of drug use for PCOS; Ocp users; No regular use of herbal medicine

Intervention groups
Intervention group:receive the combination therapy with extract of Bunium Persicum and Foeniculum Vulgare for four months twice a day

Main outcome variables
Menstrual pattern

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120709010222N20**
Registration date: **2018-11-14, 1397/08/23**
Registration timing: **registered_while_recruiting**
Last update: **2018-11-14, 1397/08/23**
Update count: **0**

Registration date
2018-11-14, 1397/08/23

Registrant information

Name
Zahra Keivani

Name of organization / entity
Shahrekord University Of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 38 1222 0016

Email address
keivani@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evalution of the effect of combination therapy with extract of Bunium Persicum and Foeniculum Vulgare on clinical features in Polycystic Ovary Syndrome (PCOS) patients

Public title
Evalution of the effect of combination therapy with

extract of Bunium Persicum and Foeniculum Vulgare on clinical features in Polycystic Ovary Syndrome (PCOS) patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Polycystic ovary syndrome

Exclusion criteria:

History of drug use for PCOS Ocp users No regular use of herbal medicine

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

70people who have been admitted to the study, who had been previously visited by the doctor, are divided into two groups of 35 members by randomly assigned random numbers.Blocked randomization is intended to ensure that exactly the same number of participants participates in consecutive but equal intervals, into three groups.The size of each block in this study is 35.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and the patient will have no information about the content of the capsules

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Vice Chancellor of Research and Technology, Shahrekord University of Medical Sciences,Kashani Blvd, Shahrekord,Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2018-09-23, 1397/07/01

Ethics committee reference number

IR.SKUMS.REC.1397.162

Health conditions studied

1

Description of health condition studied

Pcos

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Menstrual pattern

Timepoint

every months

Method of measurement

checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to routine drugs,receive the combination of extract of Bunium Persicum and Foeniculum Vulgare for four months twice a day.

Category

Treatment - Drugs

2

Description

Control group: In addition to routine drugs, they receive a placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person
Belgheyse Mohammadi
Street address
Kashani Hospital of Shahrekord University of Medical Sciences, Parastar street, Shahrekord, Iran
City
shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3222 0016
Email
mohammadi.b@skums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Shahrekord University of Medical Sciences
Full name of responsible person
Belghese Mohammadi
Street address
Kashani Hospital of Shahrekord University of Medical Sciences, Parastar street, Shahrekord, Iran
City
shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3222 0016
Email
mohammadi.b@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Shahrekord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Belghese Mohammadi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Kashani Hospital of Shahrekord University of Medical Sciences, Parastar street, Shahrekord, Iran
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3222 0016
Email
mohammadi.b@skums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Belghese Mohammadi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Kashani Hospital of Shahrekord University of Medical Sciences, Parastar street, Shahrekord, Iran
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3222 0016
Email
mohammadi.b@skums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Belghese Mohammadi
Position
Assistant professor
Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kashani Hospital of Shahrekord University of Medical Sciences, Parastar street, Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3222 0016

Email

mohammadi.b@skums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total data in article format

When the data will become available and for how long

1397

To whom data/document is available

researcher

Under which criteria data/document could be used

publication

From where data/document is obtainable

journals

What processes are involved for a request to access data/document

publication of article

Comments