

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Evaluation 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 intervention 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

Evaluation 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

Evaluation 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**

70 people 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

**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

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**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**

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**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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Belghese Mohammadi

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

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**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**