# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Evaluation of the effect of a combination product based on Vitex agnus castus herb compared to Dydrogesterone drug on oligomenorrhea caused by polycystic ovary syndrome: A randomized, triple-blind, clinical trial

## Protocol summary

**Study aim**

*A) General Objective: To determine the efficacy of a combination product based on Chasteberry (Vitex agnus-castus*) compared to Dydrogesterone on oligomenorrhea caused by Polycystic Ovary Syndrome (PCOS)

**Design**

Patients will be randomly assigned to two groups (control and intervention) using block randomization in blocks of four. Randomization will be performed using a random allocation list generated by Excel. The study will be conducted in a triple-blind manner (blinding the patient, the primary investigator, and the statistical analyst). To ensure blinding, Dydrogesterone and the herbal medication will be randomly assigned codes A and B; these codes will only be revealed after the statistical analysis is completed to prevent performance and information bias. The control group will receive 10 mg of Dydrogesterone, while the intervention group will receive a herbal capsule formulated from Chasteberry (including Vitex agnus-castus* seeds, Daucus carota seeds, and Mentha pulegium leaves). Furthermore, Dr. Samira Eghbali, a faculty member at the School of Pharmacy, Birjand University of Medical Sciences, is designated to handle the coding of medications and patients to maintain the triple-blind integrity of the study

**Settings and conduct**

Gynecology clinics at Valiasr Hospital and Rouyesh Infertility Center, Birjand, during 2026-2027.

**Participants/Inclusion and exclusion criteria**

Women18-45age with pco

**Intervention groups**

chemical drog and herbal drog

**Main outcome variables**

Incidence of menstrual bleeding and regularization of cycles.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20251224068427N1**
Registration date: **2026-04-15, 1405/01/26**
Registration timing: **prospective**

Last update: **2026-04-15, 1405/01/26**
Update count: **0**

**Registration date**

2026-04-15, 1405/01/26

**Registrant information**

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**Name of organization / entity**

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**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-04-21, 1405/02/01

**Expected recruitment end date**

2027-10-23, 1406/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Evaluation of the effect of a combination product based on Vitex agnus castus herb compared to Dydrogesterone drug on oligomenorrhea caused by polycystic ovary syndrome: A randomized, triple-blind, clinical trial

**Public title**
Comparison of the efficacy of a Chasteberry-based herbal medicine with Dydrogesterone in the treatment of Polycystic Ovary Syndrome (PCOS)

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
All patients aged 18 to 45 years with PCOS presenting with symptoms of oligomenorrhea to the gynecology clinics of Valiasr Hospital and Rouyesh Infertility Center in Birjand, who have been diagnosed with PCOS by a gynecologist using the Rotterdam criteria, will be included. Malignancies, pregnancy, and other hormonal causes of oligomenorrhea must be ruled out at baseline, ensuring that oligomenorrhea is solely due to PCOS. Furthermore, patients who are reluctant to use conventional chemical drugs or invasive/semi-invasive procedures, and for whom the gynecologist deems traditional medicine treatment and a 12-week observation period without conventional interventions safe and non-detrimental, will be voluntarily referred to the researcher. Participants will enter the study after providing informed consent.

**Exclusion criteria:**
1. Co-morbid diabetes, dyslipidemia, or hypertension.2. Presence of treated or clinical hyper/hypothyroidism.3. Co-existing hyper/hypoprolactinemia.4. Concurrent cardiac, hepatic, renal, or adrenal diseases.5. Presence of Cushing's syndrome.6. Use of ovulation-inducing drugs within the last three months.7. Use of insulin-stimulating medications within the last three months.8. Pregnant or breastfeeding women with infants under 6 months of age.9. Women planning to become pregnant within the next three months.10. Patient's withdrawal of consent to continue treatment.11. Occurrence of allergic reactions to the medications used in the study, particularly to the Apiaceae (Umbelliferae) family.

**Age**
From **18 years** old to **45 years** old

**Gender**
Female

**Phase**
3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients will be randomly assigned to two groups(control and intervention) using block randomization in blocks of four. Randomization will be performed using a random allocation list generated by Excel. The study will be conducted in a triple-blind manner (blinding the patient, the primary investigator, and the statistical analyst). To ensure blinding, Dydrogesterone and the herbal medication will be randomly assigned codes A and B; these codes will only be revealed after the statistical analysis is completed to prevent performance and information bias. The control group will receive 10 mg of Dydrogesterone, while the intervention group will receive a herbal capsule formulated from Chasteberry (including Vitex agnus-castus* seeds, Daucus carota seeds, and Mentha pulegium leaves). Furthermore, Dr. Samira Eghbali, a faculty member at the School of Pharmacy, Birjand University of Medical Sciences, is designated to handle the coding of medications and patients to maintain the triple-blind integrity of the study.

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**
The study will be conducted in a triple-blind manner (blinding the patient, the primary investigator, and the statistical analyst). To ensure blinding, Dydrogesterone and the herbal medication will be randomly assigned codes A and B; these codes will only be revealed after the statistical analysis is completed to prevent performance and information bias.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Birjand University of Medical Sciences.

**Street address**
ghaffari ave.

**City**
birjand

**Province**
South Khorasan

**Postal code**
۹۷۱۷۸۵۳۰۷۶

**Approval date**
2026-03-09, 1404/12/18

**Ethics committee reference number**
IR.BUMS.REC.1404.538

## Health conditions studied

**1**

**Description of health condition studied**
Polycystic Ovary Syndrome (PCOS).
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
incidence of menstrual bleeding and regularization of cycles.
**Timepoint**
THREE menstrua cycles
**Method of measurement**
The study participants will be divided into two groups of 30: Group A (herbal intervention) and Group B (Dydrogesterone 10 mg). *Group A will receive an herbal formulation based on Aslaq (comprising Daucus carota* seeds, Mentha pulegium, and Vitex agnus-castus), with the dosage adjusted according to Persian Medicine (PM) pharmacopeia, administered in two divided doses for three weeks (starting from day 7 of the menstrual cycle). *Group B will be treated with Dydrogesterone (10 mg/day) during the last ten days of their menstrual cycle. The intervention in both groups will be repeated for three consecutive menstrual cycles. A follow-up will be conducted in the fourth month (without medication) to evaluate the incidence and regularity of menstruation. The Higham Chart (Pictorial Blood Loss Assessment Chart, PBAC) will be utilized to determine the volume of menstrual bleeding

## Secondary outcomes

**1**

**Description**
Menstrual bleeding volume, duration, and cycle length are considered *secondary outcomes. The changes in FSH, LH, Prolactin, TSH, Free Testosterone levels, and the LH/FSH ratio will be assessed and analyzed at both baseline and the end of the intervention. Furthermore, clinical improvements in hyperandrogenism symptoms, including acne and hirsutism (evaluated using the Ferriman-Gallwey score), will be recorded at the beginning and end of the study. Patient satisfaction with the treatment will be assessed at the end of the third month using the Visual Analogue Scale (VAS). Additionally, potential adverse drug reactions (ADRs) will be monitored and documented via a structured checklist
**Timepoint**
Three menstrual cycles per patient.
**Method of measurement**
The changes in *FSH, LH, Prolactin, TSH, Free Testosterone levels, and the LH/FSH ratio will be analyzed at baseline and at the end of the intervention. Furthermore, clinical improvements in hyperandrogenism-related symptoms, specifically acne and hirsutism (evaluated via the Modified Ferriman-Gallwey (mFG) score), will be assessed at the beginning and end of the study. Patient satisfaction with the treatment will be measured at the end of the third month using the Visual Analogue Scale (VAS). Potential adverse drug reactions will be monitored and recorded using a structured checklist.Statistical Analysis:Qualitative data will be described using frequency tables, while quantitative data will be presented as mean ± standard deviation (SD) or median (interquartile range, IQR). Data normality will be assessed using the Kolmogorov-Smirnov (K-S) test. For the comparison of qualitative variables, the Chi-square test or Fisher's exact test will be employed. To compare quantitative data between the two groups, the Independent T-test or Mann-Whitney U test will be utilized. If the sample size is sufficient, Analysis of Covariance (ANCOVA) or logistic regression will be used to control for confounding factors, depending on the nature of the dependent variable. All statistical analyses will be performed using SPSS software (version 22), with a significance level of $p < 0.05$

## Intervention groups

**1**

**Description**
Intervention group:30 Women aged 18 to 45 years with *Polycystic Ovary Syndrome (PCOS) who will receive herbal treatment based on *Vitex agnus-castus* for three menstrual cycles.for 21 days in each cycle, excluding the menstrual period.
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group: 30 women aged 18 to 45 years with *PCOS who will receive chemical treatment with Dydrogesterone (10 mg) for three menstrual cycles, administered during the last ten days of each cycle.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
The Gynecology Clinics of *Vali-e-Asr Hospital
**Full name of responsible person**
dr. hossein dehghani
**Street address**
ghaffari ave.
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Birjand University of Medical Sciences
**Proportion provided by this source**
1
**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**
Birjand University of Medical Sciences
**Full name of responsible person**
fahimeh zangooei
**Position**
resident in PHD of persian medicine
**Latest degree**
Medical doctor
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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Faculty member
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## Person responsible for updating data

**Contact**
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**Latest degree**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
Due to confidentiality requirements
**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**
The data will be made available in the associated
**When the data will become available and for how long**
Data will be available following the completion of the clinical trial and subsequent publication of the result
**To whom data/document is available**
Researchers and investigators
**Under which criteria data/document could be used**
To facilitate future clinical trials While maintaining document confidentiality
**From where data/document is obtainable**
DR. Fahimeh Zangooei
**What processes are involved for a request to access data/document**
Data requests may be directed to Dr. Zangooei through email. Access will be granted to authorized researchers upon successful academic identity verification
**Comments**