Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Traditional Medicine product and metformin and Traditional Medicine product with metformin on menstrual bleeding events in patients with polycystic ovary syndrome complaint oligomenorrhea

Protocol summary

Summary

The general goal: Comparison of product derived from Traditional Medicine with metformin in oligomenorrhea in patients with polycystic ovarian syndrome. Design: three-group clinical trial. Study population: Women with polycystic ovary syndrome their complaint is oligomenorrhea. Inclusion and exclusion criteria: Age 40-18 years with PCOS confirmed by gynecologist their complaint is oligomenorrhea and no other systemic disease. Patients in the event of pregnancy, the use of steroids and the need for other interventions during treatment or personal taste are excluded. The sample size of 33 patients in each group with respect to the pilot data and a total of 100 patients including the loss of 41 patients in each group and a total of 120 people. Intervention time: 3 months and one month follow-up. The outcome of the study is incidence of bleeding, bleeding volume and bleeding time.

General information

Acronym

PCOS

IRCT registration information

IRCT registration number: **IRCT2015042521937N1**
Registration date: **2015-07-21, 1394/04/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-21, 1394/04/30

Registrant information

Name

Maryam Bahman

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-07-01, 1394/04/10

Expected recruitment end date

2016-06-30, 1395/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Traditional Medicine product and metformin and Traditional Medicine product with metformin on menstrual bleeding events in patients with polycystic ovary syndrome complaint oligomenorrhea

Public title

Comparison of the effect of a product from Traditional Medicine with Metformin on oligomenorrhea in polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with PCOS their main complaint is oligomenorrhea. Age 40-18 years, patient satisfaction, the absence of any systemic disease such as hyperinsulinemia, hyperandrogenism, diabetes mellitus, Cushing syndrome, congenital adrenal hyperplasia, hyperprolactinemia and hyperthyroidism, hypertension, lack of pregnancy or within 6 weeks post-partum, lack of breastfeeding, non-hormonal drugs in the last month, no family history of breast and ovarian cancer. Exclusion criteria: Hormone therapy use, side effects, the need for other interventions and surgery, pregnancy occurred during the study, the patient's own request for exclusion.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients were randomly divided into three groups: product of Traditional Medicine, metformin, product of Traditional Medicine with metformin.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Beheshti University of Medical Sciences

Street address

Velenjak St, Shahid Chamran highway, Shahid Beheshti university of Medical Sciences

City

Tehran

Postal code

Approval date

2015-06-14, 1394/03/24

Ethics committee reference number

SBMU.REC.1394.80

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

Experience of menstural bleeding

Timepoint

Before intervention and 3, 4 month after intervention

Method of measurement

Question from patient

2

Description

Duration of bleeding

Timepoint

Before the intervention, month 3, 4

Method of measurement

Ask the patient

3

Description

Menstrual blood volume

Timepoint

Before the intervention, month 3,4

Method of measurement

Pictorial Blood Loss Assessment Chart (PBAC)

Secondary outcomes

1

Description

Added at 2016-07-02: interval between menstural periods

Timepoint

Added at 2016-07-02: Before the intervention and 1, 2, and 3 months after the intervention

Method of measurement

Added at 2016-07-02: Asking from patients

Intervention groups

1

Description

Group 3: Traditional product 2 capsules in the morning and 2 nights during the month, except during the period plus metformin 500 mg tablets after every meal during month.

Category
Treatment - Drugs

2

Description
Group 2: Metformin 500 mg tablets after every meal during month
Category
Treatment - Drugs

3

Description
Group 1: Traditional medicine product 2 capsules in the morning and 2 nights during the month, except during the period
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Traditional Medicine and Materia Medica Research Center Shahid Beheshti
Full name of responsible person
Maryam Bahman
Street address
No.8 Shams Alley, opposite Street Tavanir, Vali Asr Street, Tehran
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2

Recruitment center
Name of recruitment center
Private clinic of Mrs Soodabe Bioos
Full name of responsible person
Maryam Bahman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
School of Traditional Medicine and Materia Medica Research Center Shahid Beheshti
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Mojgan Tansaz M.D. Ph.D, Assistant Professor
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No.8 Shams Alley, Opposite Street Tavanir, Vali Asr Street, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
School of Traditional Medicine and Materia Medica Research Center Shahid Beheshti
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
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Person responsible for scientific inquiries

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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