

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the effects of Bromocriptine and Metformin on the treatment of menstrual pattern in young women with polycystic ovary syndrome

Protocol summary

Summary

Objectives: Comparison of effect of Bromocriptine and Metformin on the menstrual cycle in young women with polycystic ovary. Design: Randomized, single-blind, single-center, phase II trial. Setting and conduct: Group A, 2.5 mg per day Bromocriptin is administered. Group B, two 500 mg Metformin pills per day is administered. Participants including major eligibility criteria: Inclusion criteria include presence of polycystic ovary; exclusion criteria include marriage. Intervention: Group A, 2.5 mg per day Bromocriptin is administered. Group B, two 500 mg Metformin pills per day is administered. Main outcome measures variable: menstrual cycle is evaluated after consumption of drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512313461N7**
Registration date: **2016-03-16, 1394/12/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-16, 1394/12/26

Registrant information

Name

Firoozeh Veisi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2015-12-31, 1394/10/10

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Bromocriptine and Metformin on the treatment of menstrual pattern in young women with polycystic ovary syndrome

Public title

effects of Bromocriptine and Metformin on polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : menstrual cycles greater than 40 days; acnea; hirsutism; pco on sonography; LH/FSH ratio greater than 2; normal prolactin; normal TSH; excess androstenedione; normal blood sugar. Exclusion criteria: marriage; psychiatric drug users; professional athletes; primary amenorrhea; history of chronic illnesses; body mass index greater than 30 kg/m2.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of kermanshah University of Medical Sciences

Street address

Vice chancellor for Research, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd

City

Kermanshah

Postal code**Approval date**

2015-09-23, 1394/07/01

Ethics committee reference number

Kums.REC.1394.220

Health conditions studied**1****Description of health condition studied**

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Menstrual pattern

Timepoint

Before , 3 and 6 months after intervention

Method of measurement

Questionnaire, menstrual cycle days measurement

Secondary outcomes

empty

Intervention groups**1****Description**

Group 1 : 5 mg of bromocriptine daily is administered . In the first week 1.25 mg and after that 1.25 mg weekly is added until 5 mg per day.

Category

Treatment - Drugs

2**Description**

Group 2 : a daily dose of 1000 mg of metformin is administered. In the first week 250 mg and after that 250 mg weekly is added until to 2 pills a day.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Sahar Oskouie

Street address

Gynecologic clinic, Parastar Blvd, Imam Reza hospital

City

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Behroz Hamzeh

Street address

Shahid Beheshti Blvd, Building No 2, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Kermanshah 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**

Vice chancellor for research, Kermanshah University of Medical Sciences, Kermanshah, Iran

Full name of responsible person

Firoozeh Veisi

Position

Associated professor, faculty member

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Full name of responsible person

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Fax**Email****Web page address****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