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

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