

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Cabergoline plus metformin therapy effects on menstrual irregularity and androgen system in polycystic ovary syndrome women with hyperprolactinaemia

Protocol summary

Summary

Objective: To investigate the adjuvant cabergoline therapy effects on menstrual irregularity and androgen system in polycystic ovary syndrome women with hyperprolactinemia. **Materials and methods:** This randomized clinical trial was done on 110 PCOS women with increased serum prolactin concentration [1.5 fold more than normal level (>37.5ng/ml)]. Participants were divided into two groups: Case group (n=55) treated with metformin 1gr/day and cabergoline 0.5 mg/week for 4 months and control group (n=55) treated with metformin 1g/day and placebo weekly. Testosterone, prolactin, and DHEAS level were measured before and four months after intervention in two groups. Also, situation of menstrual cycles asked and recorded before and after intervention. **Inclusion criteria:** 110 PCOS women with increased serum prolactin concentration [1.5 fold more than normal level (>37.5ng/ml)], who referred to endocrinology clinic of Khatamal Anbiaa Cilinic, Shahid Sadoughi University of Medical Sciences, were examined for other causes of increased prolactin levels such as TSH test, hypophis MRI for detection of prolactinoma and other disorders or tumors that can increase prolactin, and then women who had diagnosed as PCOS according to the latest AES standards enrolled in the study. **Exclusion criteria:** Patients who had other endocrine disorders (such as thyroid disorders), history of cardiovascular disease, history of using the increasing prolactin drugs, women who wanted to be pregnant, and who couldn't tolerate the cabergoline were excluded from the study. **Primary outcome measure:** Menstrual irregularity, and laboratory findings (serum testosterone, DHEAS and prolactin). **Secondary outcome measure:** Weight

General information

Acronym

Cabergoline in PCOS women

IRCT registration information

IRCT registration number: **IRCT2014121420086N2**

Registration date: **2015-01-08, 1393/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-08, 1393/10/18

Registrant information

Name

Parisa Khani

Name of organization / entity

Yazd research and clinical center for infertility

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cabergoline plus metformin therapy effects on menstrual irregularity and androgen system in polycystic ovary syndrome women with hyperprolactinaemia

Public title

Effect of cabergoline on laboratory findings and menstrual irregularity in PCOS women

Purpose

Treatment

Inclusion/Exclusion criteria

110 PCOS women with increased serum prolactin concentration [1.5 fold more than normal level (>37.5ng/ml)]; between 18-35 years old, who referred to endocrinology clinic of Khatamal Anbiaa Cilinic, Shahid Sadoughi University of Medical Sciences, were examined for other causes of increased prolactin levels such as TSH test, hypophis MRI for detection of prolactinoma and other disorders or tumors that can increase prolactin, and then women who had diagnosed as PCOS according to the latest AES standards enrolled in the study. Patients who had other endocrine disorders (such as thyroid disorders), history of cardiovascular disease, history of using the increasing prolactin drugs, women who wanted to be pregnant, and who couldn't tolerate the cabergoline were excluded from the study.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Sciences-
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City

Yazd

Postal code

8915173149

Approval date

2012-06-17, 1391/03/28

Ethics committee reference number

41511/1/17/پ

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

Polycystic ovary syndrom

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

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

menstrual irregularity

Timepoint

at the beggining of study and 4 months after intervention

Method of measurement

standard questionnaire

2**Description**

Serum testosterone

Timepoint

at the beggining of study and 4 months after intervention

Method of measurement

enzyme-linked radio immune sorbent assay (ELISA)

3**Description**

Serum DHEAS

Timepoint

at the beggining of study and 4 months after intervention

Method of measurement

enzyme-linked radio immune sorbent assay (ELISA)

4**Description**

Serum prolactin

Timepoint

at the beggining of study and 4 months after intervention

Method of measurement

enzyme-linked radio immune sorbent assay (ELISA)

Secondary outcomes**1****Description**

Weight

Timepoint

at the beginning of study and 4 months after intervention

Method of measurement

With SECA scale per kilogram

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

In case group metformin 1000 mg/day Cabergoline, 0.5 ml tablet one/week for 4 months was given.

Category

Treatment - Drugs

2**Description**

In control group metformin 1000 mg/day and cabergoline placebo weekly for 4 months were given.

Category

Placebo

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

Shahid sdoughi university of medical sciences- Khatamal Anbiaa Cilinic

Full name of responsible person

Akram Jowkar

Street address

Shahid sadoughi hospital- Endocrine department

City

Yazd

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

Shahid sdoughi university of medical sciences

Full name of responsible person

Dr. Amirhooshang Mehrparvar

Street address

Shahid sadoughi hospital

City

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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

Shahid sdoughi 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**

Shahid sdoughi university of medical sciences

Full name of responsible person

Dr.Akram Jowkar

Position

endocrinologist

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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