

# 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 ( $>37.5\text{ng/ml}$ )]. 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 ( $>37.5\text{ng/ml}$ )], 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)

###### **Phone**

+98 35 3824 8348

###### **Email address**

pkhani55@ssu.ac.ir

##### **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-  
Bahonar sq- Yazd

**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

Yazd

## 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

#### Other areas of specialty/work

#### Street address

Shahid sdoughi hospital-Department of Endocrinology

#### City

Yazd

#### Postal code

#### Phone

+98 35 3822 4000

#### Fax

#### Email

akjowkar@gmail .com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid sdoughi university

#### Full name of responsible person

Dr.Akram Jowkar

#### Position

Endocrinologist

#### Other areas of specialty/work

#### Street address

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Yazd

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#### Phone

+98 35 3822 4000

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akjowkar@gmail.com

**Web page address**

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

endocrinology department-Shahid sdoughi University  
of medical sciences

**Full name of responsible person**

Dr.Akram Jowkar

**Position**

Endocrinologist

**Other areas of specialty/work**

**Street address**

Shahid sdoughi hospital-Department of Endocrinology

**City**

Yazd

**Postal code**

**Phone**

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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*