

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effect of Bromocriptin on insulin resistance in comparison with placebo in patients with polycystic ovaries referring to Golestan Hospital of Ahvaz.

#### Protocol summary

##### Summary

This study is a controlled, randomized and single-blind clinical trial that is performed on 44 patients with polycystic ovaries between 16 and 45 years old and Body Mass Index more than 25. Patients who are diabetic, hypothyroidism, nonclassic congenital adrenal hyperplasia or prolactinoma will be excluded. All of the patients should signed informed consent for taking either Bromocriptin or placebo; but, they will not be aware which group of study (experimental or control) have been entered. Patients participating in this research, randomly select a numbered card in sealed envelopes in order to enter the control or the experimental group. Giving the medication and randomization process are done by researcher, accordingly, this study is single-blind. At the beginning of the study, fasting blood sugar and fasting insulin are measured as a basis to the prescription of medication or placebo in both groups. Measurement of fasting blood sugar and fasting insulin are done through Glucose Oxidase and Chemiluminescence methods, respectively. Then the main group is given 2.5 milligram of Bromocriptin once daily for 8 days to be taken after meal. The control group is given placebo tablets similar to Bromocriptin once daily for 8 days. Placebo is similar to that of Bromocriptin tablets in terms of shape, colour and flavor. Its components include: micro-crystalline cellulose, lactose, starch, sorbitol and magnesium stearate. To control the correct use of medications, pills and placebos are given to patients and at the end of study, the empty blisters of pills are collected and controlled. If a patient has severe nausea and vomiting, she will be excluded from study. Upon completion of study period (8 days), fasting blood sugar and fasting insulin are measured again, in both groups, using the above mentioned methods. Finally the collected data will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013030412699N1**

Registration date: **2014-01-24, 1392/11/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-01-24, 1392/11/04

##### Registrant information

##### Name

Zivar Shirinpour

##### Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1374 3013

##### Email address

shirinpour.z@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jondishapour University of Medical Sciences.

##### Expected recruitment start date

2013-02-07, 1391/11/19

##### Expected recruitment end date

2013-09-21, 1392/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effect of Bromocriptin on insulin resistance in comparison with placebo in patients with polycystic ovaries referring to Golestan Hospital of Ahvaz.

**Public title**

Effect of Bromocriptin in treatment of patients with polycystic ovaries.

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Patients with polycystic ovaries between 16 and 45 years old and Body Mass Index (BMI) more than 25. Exclusion criteria: Fasting blood sugar more than 126, hypothyroidism, prolactinoma, nonclassic congenital adrenal hyperplasia, psychosis, breast feeding, syncope attack, severe nausea and vomiting.

**Age**

From **16 years** old to **45 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

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

Single blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Vice Chancellery for Development, Research and Technology of Ahvaz Jondishapour

**Street address**

Vice Chancellery for Development, Research and Technology of Ahvaz Jondishapour University of Medical Sciences, University city, Golestan St.

**City**

Ahvaz

**Postal code**

6135733118

**Approval date**

2013-02-23, 1391/12/05

**Ethics committee reference number**

ETH695

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

Polycystic Ovary Syndrome

**ICD-10 code**

E28.2

**ICD-10 code description**

Stein Leventhal Syndrome

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

Blood Sugar

**Timepoint**

Before intervention and 8 days after intervention

**Method of measurement**

mg /dl with Glucose Oxidase method

**2****Description**

Fasting Insulin

**Timepoint**

Before intervention and 8 days after intervention

**Method of measurement**

micIU/ml, with chemiluminescence method

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

Dizziness

**Timepoint**

Before intervention and daily during intervention

**Method of measurement**

Asking from patients

**2****Description**

Nausea and vomiting

**Timepoint**

Before intervention and daily during intervention

**Method of measurement**

Asking from patients

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

Intervention Group: Bromocriptin with trade name cyclocet, made by Iran Hormone-Tehran company, gives

once daily per oral for 8 days.

**Category**

Treatment - Drugs

**2****Description**

Control Group: Placebo as 2.5 milligram tablet, once daily per oral for 8 days. Placebo is made from micro-crystalline cellulose, lactose, starch, sorbitol and magnesium stearate which made in pharmacology school of Ahvaz Jondishapour University of Medical Sciences.

**Category**

Placebo

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

Endocrinology clinic of Golestan Hospital

**Full name of responsible person**

Zivar Shirinpour, Fellowship of Endocrinology

**Street address**

Endocrinology clinic , Golestan Hospital , Golestan St.

**City**

Ahvaz

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

Vice Chancellor for Development, Research and Technology of Ahvaz Jondishapour University of Medical

**Full name of responsible person**

Mostafa Fegghi

**Street address**

Vice Chancellor for Development, Research and Technology of Ahvaz Jondishapour University of Medical Sciences, University city, Golestan St.

**City**

Ahvaz

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

Yes

**Title of funding source**

Vice Chancellor for Development, Research and Technology of Ahvaz Jondishapour University of Medical

**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**

Ahvaz Jondishapour University of Medical Sciences

**Full name of responsible person**

Homeira Rashidi

**Position**

Associated professor of Endocrinology

**Other areas of specialty/work****Street address**

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Golestanhospital@ajums.ac.ir

**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*