

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**

Endocrinology ward, Golestan Hospital, Golestan St.

City

Ahvaz

Postal code

6135733118

Phone

+98 61 1374 3013

Fax

+98 61 1374 3030

Email

Golestanhospital@ajums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Zivar Shirinpour

Position

Fellowship of Endocrinology

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

Endocrinology ward, Golestan Hospital, Golestan St.

City

Ahvaz

Postal code

6135733118

Phone

+98 61 1374 3013

Fax

+98 61 1374 3030

Email

Golestanhospital@ajums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Seyed Bahman Ghaderian

Position

Associated professor of Endocrinology

Other areas of specialty/work

Street address

Endocrinology ward, Golestan Hospital, Golestan St.

City

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Postal code

6135733118

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Fax

+98 61 1374 3030

Email

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