

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of Flutamide and Metformin administered in dieting overweight-obese women with polycystic ovary syndrome

Protocol summary

Summary

Eighty overweight obese women with PCOs were enrolled in the study according to inclusion and exclusion critical. A physical examination, focusing on anthropometry and hirsutism evaluation, was performed at base line. These Lab test were asked for them: FBS, SHBG, Total testosterone, free Total Cholesterol, TG, HDL, LDL, DHEAS, testosterone, fasting Insulin and OGTT. Women were placed on a hypocaloric diet C1200-1400 Kcal/daily containing 50% carbohydrates, 30% Lipids and 20% Proteins. They were advised to have contraception and after one month they were visited and randomly placed on 4 groups: placebo (n=20), Metformin (500 mg/TDS, n=20), Flutamide (250 mg/BID, n=20) and both Metformin and Flutamide. They were regularly checked at monthly intervals to evaluate compliance with both dietary and pharmacological treatment, and side-effects. If having no problem, each woman took her intervention for 1-month again. At the end of third month LFI and renal function test were done. At the end of 6th month, physical examination focusing on anthropometry and hirsutism were done and all first labs were asked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807271760N3**

Registration date: **2010-05-21, 1389/02/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-21, 1389/02/31

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health
Research Center, Babol University of Medical
Sciences

Country

Iran (Islamic Republic of)

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zahra@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and technology, Babol
University of Medical Sciences

Expected recruitment start date

2008-05-21, 1387/03/01

Expected recruitment end date

2009-08-23, 1388/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Flutamide and Metformin administered in
dieting overweight-obese women with polycystic ovary
syndrome

Public title

Effect of Flutamide and Metformin administered in
dieting overweight-obese women with polycystic ovary
syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Reproductive age (range 18-45 yr),

body mass index (BMI) at least 28 kg/m², and waist circumference at least 88 cm, chronic an ovulation severe oligomorrhea or amenorrhea, hirsutism (Ferriman – Gallwey score 8), total testosterone levels at least 0.72 ng/ml and polycystic ovarian morphology at ultrasound. Exclusion criteria: Use of any medication or a significant modification in body weight within the previous 3 months or dieting, hyperprolactinemia, cushing’s syndrome, late-onset congenital adrenal hyperplasia, thyroid dysfunction, diabetes, cardiovascular, renal or Liver diseases, positive pregnancy test.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Ethics committee of Babol University of Medical sciences

Street address

Gangafroz Avenue

City

Babol

Postal code**Approval date**

2010-02-27, 1388/12/08

Ethics committee reference number

1009

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

Polycistic overian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycistic overian syndrome

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

Anthropometric measurement

Timepoint

monthly

Method of measurement

physical examination

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

serum Lipid

Timepoint

monthly

Method of measurement

Lab

2**Description**

serum glucose

Timepoint

monthly

Method of measurement

lab

3**Description**

fasting insulin

Timepoint

6 months

Method of measurement

lab

4**Description**

testosterone, OHEA, SHBG

Timepoint

6 months

Method of measurement

lab

5**Description**

hirsotism

Timepoint

6 months

Method of measurement

physical examination

Intervention groups

1

Description

Flutamide and/or Metformin

Category

Treatment - Drugs

2

Description

Hypocaloric dieting

Category

Lifestyle

3

Description

Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemehzahra Fertility & infertility hospital

Full name of responsible person

Sedigheh Esmaeilzadeh

Street address

Noshirvani street

City

Babol

2

Recruitment center

Name of recruitment center

Yahyanejad hospital

Full name of responsible person

Dr. Seddigheh Esmaeilzadeh

Street address

Farhang cross

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Gangafroz Avenue

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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

Vice Chancellor for Research and Technology, Babol
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

Fatemehzahra Fertility & reproductive Health
Research Center

Full name of responsible person

Nargess Gholizadeh Pasha

Position

M.A/responsible of Reseach Center

Other areas of specialty/work

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Other areas of specialty/work

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Web page address**Person responsible for updating data****Contact****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