Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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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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
testosteroe, 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
Seddigheh 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
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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
City
Babol
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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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