Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of combined oral contraceptive Yasmin and Cyproteron compound on Hirsutism and androgens in women with a polycystic ovary syndrome

Protocol summary

Summary

This randomized clinical trial is conducted on 100 women (18-28 years old) with a diagnosis of polycystic ovary syndrome (PCOS) with Hirsutism who are referred to our researcher center for treatment of disease and taking contraceptive necessities. PCOS is defined as diagnostic criteria of 2003 census Rotterdam. Hirsutism is defined as the presence of excessive hair in body and Ferriman –Gallway score >=8. The ultrasound examination of the uterus and ovaries is performed with using a multi frequency trans-abdominal transducer (Esaote My Lab 40). Endometrial thickness, ovarian volume, number Struma are recorded. Blood samples for serum FSH, LH, free testosterone, androstendion, 17-hydroxy progesterone (17 -OHP), and sex hormone binding globulin are taken at baseline and at the end of the treatment at the early follicular phase between 4th to 5th days of menstrual cycle at 8 Am. FSH/ LH concentration ratio and free androgen index (FAI) are calculated. The women are randomly allocated to oral treatment with Yasmin (Drospirenone 3 mg+ 30 EE µg) through days 1-21 of menstrual cycle (group 1; n= 50) or Cyproteron compound (2 mg Cyproteron acetate + 35 µg EE) through days 1-21 of menstrual cycle (group 2; n= 50). The women are studied at the baseline condition and after 6 month of therapy. Women will participate in the study after an informed written consent.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104251760N13**
Registration date: **2012-03-04, 1390/12/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-03-04, 1390/12/14

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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+98 11 3236 2282

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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

2012-02-20, 1390/12/01

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of combined oral contraceptive Yasmin and Cyproteron compound on Hirsutism and androgens in women with a polycystic ovary syndrome

Public title
Comparison of combined oral contraceptive Yasmin and Cyproteron compound on Hirsutism and androgens in women with a polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 18-28 years old nonsmoker women with polycystic ovary syndrome and Hirsutism who are raftered to our research center for treatment of Hirsutism and taking contraceptive necessities. Exclusion criteria: Hyper-prolactinemia; Hypothyroidism; diabetes; doing regular intense exercise; taking diet or herbal treatment, Non-steroidal anti- inflammatory drugs, diuretics, or hormone therapy during last 3 months.
Age
From **18 years** old to **28 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The ethics committee of Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Gangafroz Avenue
City
Babol
Postal code
Approval date
2012-02-13, 1390/11/24
Ethics committee reference number
5720

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

2

Description of health condition studied
Hirsutism
ICD-10 code
L68
ICD-10 code description
Hypertrichosis

Primary outcomes

1

Description
Back spontaneous menstrual
Timepoint
6 months after cessation of treatment
Method of measurement
Clinical examination

Secondary outcomes

1

Description
side effects of drugs (such as complaints of headaches and spotting)
Timepoint
4 months
Method of measurement
Clinical examination

Intervention groups

1

Description
Intervention Groups: Yasmin pills (containing Drospirenone 3 mg+30 g Ethinyl Estradiol), from 1-21 day cycle for 4 months.
Category
Treatment - Drugs

2

Description
Control group: Cyproterone Compound Tablets (2 mg Cyproteron acetate + 35 µg Ethinyl Estradiol) from day 21 to 1 cycle for 4 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemeh-Zahra Fertility & infertility Medical Center

Full name of responsible person
Dr. Molood Aghajani Delavar

Street address
After Mohammad Hassan Khan Bridge, Old Road, Amol, Babol, Fatemeh-Zahra Medical Center-Fatemeh-zahra Infertility & Reproductive Health ResearchCenter

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
Vice Chancellor for Research and Technology, Babol University of Medical Sciences, 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 Infertility & reproductive Health Research Center

Full name of responsible person
Dr. Molod Aghajani-delavar

Position
PhD in Women's Health

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position
Gynecologist

Other areas of specialty/work

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Person responsible for updating data

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Fatemehzahra Infertility & Reproductive Health Research Center

Full name of responsible person
Nargess Gholizadeh Pasha

Position
M.A/Responsible for Public Affairs Research Center

Other areas of specialty/work

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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