

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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  $\geq 8$ . 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  $\mu$ g) through days 1-21 of menstrual cycle (group 1; n= 50) or Cyproteron compound (2 mg Cyproteron acetate + 35  $\mu$ g 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)

###### Phone

+98 11 3236 2282

###### Email address

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 referred 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

**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 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

**Street address**

Fatemehzahra Infertility & reproductive Health Research Center, After Mohammad Hassan Khan Bridge, old Road Amol

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moloodaghajani@yahoo.com

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Fatemeh-Zahra, Infertility & Reproductive Health Research Center

**Full name of responsible person**

Dr. Seddigheh Esmaeilzadeh

**Position**

Gynecologist

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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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****Street address**

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**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*