

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of phlebotomy and Cyproterone compound in insulin resistance, antimullerian hormone (AMH) and prostatic specific antigen (PSA) in polycystic ovarian syndrome patients

Protocol summary

Study aim

Comparing the effect of Phlebotomy and Cyproterone Compound on insulin resistance, anti-mullerian hormone, and Prostatic Specific Antigen (PSA) concentrations in patients with PCOS

Design

After obtaining informed consent, the 120 included patients were randomly allocated in a 1:1 ratio to either the iron-reduction group of phlebotomy and the cyproterone compound group, using a random number table. They didn't receive any medication.

Settings and conduct

All referred PCOS patients to Endocrine clinic, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences were randomly allocated to phlebotomy and CC groups. Phlebotomy Patients undergo venesection of 450 ml of whole blood and are advised not to use any hormonal or iron-containing medications. Cyproterone Compound group were advised three cycles of pills are prescribed. Each cycle includes 21 days of use and 7 days without pills. They should not use any other medications (e.g. hormone(s) or iron-containing drugs).

Participants/Inclusion and exclusion criteria

Inclusion criteria: PCOS patients with: 18-45 years old; Hgb more than 12; ferritin more than 20; no diabetes mellitus; no heart problem; no hypertension or under treatment; not pregnant; no thyroid problem; no cancer. Exclusion criteria: pregnancy; heart or thyroid disease; hypertension; cancer; diabetes mellitus.

Intervention groups

RCT will be performed in two groups: The study group was undergone venesection of 450 mL of whole blood. The cyproterone compound group received Cyproterone Compound pill for 3 months from day 1 of spontaneous or progesterone-induced menstrual cycle onwards for 3 weeks and followed by a pill-free interval of 7 days

Main outcome variables

Hirsutism score, HOMA-IR score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080514277N1**

Registration date: **2014-06-16, 1393/03/26**

Registration timing: **prospective**

Last update: **2018-12-14, 1397/09/23**

Update count: **1**

Registration date

2014-06-16, 1393/03/26

Registrant information

Name

Hayedeh Abtahi

Name of organization / entity

Research Institute for Endocrine Science Shaheed Beheshti University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2500

Email address

habtahii@gmail.com

Recruitment status

Recruitment complete

Funding source

Shaheed Beheshti University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

2014-06-22, 1393/04/01

Actual recruitment end date

2016-03-20, 1395/01/01

Trial completion date

2016-03-20, 1395/01/01

Scientific title

Comparison of phlebotomy and Cyproterone compound in insulin resistance, antimullerian hormone (AMH) and prostatic specific antigen (PSA) in polycystic ovarian syndrome patients

Public title

Phlebotomy in polycystic ovarian syndrome (PCOS)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

PCOS patients 18-45 years old Hgb more than 12 ferritine more than 20 free of diabetes melitus free of heart disease free of hypertension free of cancer free of thyroid problem

Exclusion criteria:

pregnancy Diabetes Cardiovascular disease Hypertension Thyroid disease cancer

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation using random number table will be performed

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of research institute for endocrine

sciences, Shaheed Beheshti University of Medic

Street address

NO 24, Parvaneh st., Yaman st., Velenjak

City

Tehran

Province

Tehran

Postal code

19395-4763

Approval date

2013-02-26, 1391/12/08

Ethics committee reference number

17ECRIES91/12/08

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

polycystic ovarian syndrom

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

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

Insulin resistance with Homeostatic Model Assessment (HOMA-IR)

Timepoint

Before intervention and immediately after intervention (3 month)

Method of measurement

Laboratory

2**Description**

Anti mullerian hormone

Timepoint

Before intervention and immediately after intervention (3 month)

Method of measurement

Laboratory assessment

3**Description**

Prostate-Specific Antigen

Timepoint

Before intervention and immediately after intervention (3 month)

Method of measurement

Laboratory

Secondary outcomes

1

Description

Hirsutism Score

Timepoint

Before intervention and immediately after intervention (3 month)

Method of measurement

clinical

2

Description

Menstrual irregularity

Timepoint

Before intervention and immediately after intervention (3 month)

Method of measurement

Questionair

Intervention groups

1

Description

Intervention group (Phlebotomy group): Patients undergo venesection of 450 ml of whole blood and are advised not to use any hormonal or iron- containing medications.

Category

Treatment - Other

2

Description

Control group: patient who randomly allocated in control group, will be received the 1 tab of cyproteron compound for 21 days (with 7 days free of tab) for 3 cycles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute for Endocrine Sciences, Shaheed Beheshti University of Medical Sciences

Full name of responsible person

Dr. Hayedeh Abtahi

Street address

NO 24, Parvaneh st. Yaman st, Velenjak

City

Tehran

Province

Tehran

Postal code

19395-4763

Phone

+98 21 2243 2500

Email

habtahii@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Endocrine Sciences

Full name of responsible person

Dr. F. Azizi

Street address

No.24,Parvaneh st., Yaman st., Velenjak

City

Tehran

Province

Tehran

Postal code

19395-4763

Phone

+98 21 2243 2500

Email

habtahii@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Institute for Endocrine Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Research Institute for Endocrine Sciences

Full name of responsible person

Dr. Navid Saadat

Position

Endocrinologist

Latest degree

Subspecialist

Other areas of specialty/work

Family Physician

Street address

NO 24, Parvaneh st , Yaman st.,Velenjak

City

Tehran

Province

Tehran

Postal code

19395-4763

Phone

+98 21 2243 2500

Fax

Email

saadat@endocrine.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Research Institute for Endocrine Sciences

Full name of responsible person

Dr. Fahimeh Ramezani Tehrani

Position

Gynecologist

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

NO 24, Parvaneh st. Yaman st., Velenjak

City

Tehran

Province

Tehran

Postal code

19395-4763

Phone

+98 21 2243 2500

Fax

Email

ramezani@endocrine.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Research Institute for Endocrine Sciences

Full name of responsible person

Dr. Hayedeh Abtahi

Position

Endocrinologist

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinologist

Street address

NO 24 , Parvaneh st. Yaman st. ,Velenjak

City

Tehran

Province

Tehran

Postal code

19395-4763

Phone

+98 21 2243 2500

Fax

Email

habtahii@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The participant data file will be encoded and will be used for final analysis. The research results will be published in the form of a paper

When the data will become available and for how long

The participant data file will be available 6 months after publishing the final paper

To whom data/document is available

Data will be available to researchers that working in academic institutions

Under which criteria data/document could be used

The names and contact numbers of the participants in the study are confidential. Other information will be available.

From where data/document is obtainable

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran

What processes are involved for a request to access data/document

The applicant must complete the application form by attending the application

Comments