Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Nov 2026

Comparison of phlebothomy 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 received any medication.

Settings and conduct
All refereed 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 pateints with: 18-45 years old; Hgb more than 12; ferritine more than 20; no diabetes melitus ; no heart problem; no hypertention or under treatment; not pregnant;no thyroid problem; no cancer. Exclusion criteria: pregnancy; heart or thyroid disease; hypertntion; cancer; diabetes melitus.

Intervention groups
RCT will be performed in two groups: The study group was undergone venesection of 450 mL of whole blood. The cyproteron 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)

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

Public title
Phelebothomy 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
Menstural 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
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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
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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
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
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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

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Latest degree

Subspecialist

Other areas of specialty/work

Endocrinologist

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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