Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparison the therapeutic effect of Clonidine, Yohimbine and Nalterexone on removing the ovarian cyst in poly-cystic ovary syndrome patients referred to Valie-Asre Clinical Center, Imam Khomeini Hospital, Tehran

Protocol summary

Summary

Women with polycystic ovary syndrome have significantly higher sympathetic nerve activity than their control groups and the increased sympathetic outflow is related to hormonal and metabolic features. Polycystic ovary is characterized by increased luteinizing hormone pulse frequency and amplitude and it is well known that one of the major neurotransmitters that control luteinizing hormone secretion is noradrenaline. The central Beta-endorphin system has a regulatory role in reproduction and autonomic functions. Beta-endorphin is inhibitory modulator of the Gonadotropin releasing hormone pulse generator and pituitary luteinizing hormone release. Thus polycystic ovary syndrome may partly result from insufficient central Beta-endorphin inhibition of Gonadotropin releasing hormone. The aim of evaluation effect of three drugs: Nalterxone, Clonidine and Yohimbine is decreasing overactivity of sympathetic nervous system. Clonidine and yohimbine are used for sympathic agonist and antagonist and Nalterxone is used for opioid system inhibition, because endogenous opioids have modulating role on cathecolamine secretion. Eighty eight women with polycystic ovary syndrome, aging 20-40 years were divided into four groups: three drug groups and one control group. Drugs are: Nalterxone capsule 0.5 mg. daily after dinner, Clonidine tablet 0.2 mg. twice0.1 mg. after breakfast and dinner and Yohimbine tablet 0.5 mg. after dinner for two mounts. The patients had no systemic medical disease, history of medication and their body mass index was less than 28.The main outcomes measurment in this study are serum levels of estradiol, FSH,LH,insuline and also adrenaline,noradrenaline, Beta-endorphine and cortisol.

General information

Acronym

polycystic ovary syndrome PCOS

IRCT registration information

IRCT registration number: **IRCT201204027883N4**
Registration date: **2012-05-23, 1391/03/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-05-23, 1391/03/03

Registrant information

Name

Farideh Zangeneh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research- Tehran University Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the therapeutic effect of Clonidine, Yohimbine and Nalterexone on removing the ovarian cyst in poly-cystic ovary syndrome patients referred to Valie-Asre Clinical Center, Imam Khomeini Hospital, Tehran

Public title
Effect of Clonidine, Yohimbine and Nalterexone on polycystic ovary syndrome patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: female, age20-40 and they are suffering of Polycystic ovary syndrome exclusion criteria:Body Mass Index:28, without basis disease and must not use drug.

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice-chanellor for research of Tehran University Medical Sciences

Street address
Central building of Tehran University of Medical Sciences

City
Tehran

Postal code

Approval date
2012-01-27, 1390/11/07

Ethics committee reference number
90-03-39-15359

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description
Estradiol,LH/FSH and Insuline

Timepoint
before intervention and after two mounts of it

Method of measurement
Utilization of diagnosis kite of Elisa

Secondary outcomes

1

Description
Adrenaline, Noradrenaline,Beta endorphine and Cortisol

Timepoint
Before intervention and two mounts of it

Method of measurement
Utilization of diagnosis Elisa kite

Intervention groups

1

Description
Nalterxone capsule 50 mg. after dinner

Category
Treatment - Drugs

2

Description
Clonidine tablet 0.2 mg. twice 0.1 mg. after breakfast and dinner.

Category
Treatment - Drugs

3

Description
Yohimbine tablet 0.5 mg. after dinner.

Category
Treatment - Drugs

4

Description
Control group: Placebo, capsule without drug.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valie Asr Reproductive Health Research Center, Tehran University of Medical Sciences.
Full name of responsible person
Dr. Farideh Zafari Zangeneh, Pharmacist,Ph.D of Physiology
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Sponsors / Funding sources

1

Sponsor
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Vice- chanellor for research, Tehran University Medical Sciences
Full name of responsible person
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Research managment, BLV. Keshavarz, , Ghods street, central building of Tehran University of Medical Sciences
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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- chanellor for research, Tehran University 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

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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