

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of sertraline on the depression and of serum prolactin levels among PCOD patients

Protocol summary

Study aim

The objective of this randomized double-blind clinical trial is to investigate the effect of sertraline on the hormonal change and depression in Polycystic ovarian syndrome (PCOS).

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

The study will be conducted among adults with major depressive disorder attending Imam Khomeini Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Women with PCOS diagnosed by the Rotterdam consensus criteria (Presence of 2 of the following 3 conditions: i. amenorrhea /oligomenorrhea ii. clinical or biochemical evidence of hyperandrogenism iii. Polycystic ovaries on ultrasound examination), 2-mild to moderate major depressive disorder based on DSM-5 criteria 3- score on hamilton depression scale equals or less than 18 4-Increased serum level of prolactin(more than 20 ng/dl) Exclusion criteria: 1-psychotic symptoms 2-presence of any other mental disorder 3-receiving any antidepressant treatment during the last 6 weeks 4-thyroid diseases 6- breast feeding or pregnancy

Intervention groups

The participants will be randomly allocated into two groups. Intervention group(20 persons) will receive sertraline (100 mg per day) and control group (20 persons) will receive placebo for 6 weeks.

Main outcome variables

Severity of depression serum level of prolactin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N123**

Registration date: **2019-10-27, 1398/08/05**

Registration timing: **prospective**

Last update: **2019-10-27, 1398/08/05**

Update count: **0**

Registration date

2019-10-27, 1398/08/05

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-05, 1398/08/14

Expected recruitment end date

2020-09-04, 1399/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sertraline on the depression and of serum prolactin levels among PCOD patients

Public title

The effect of sertraline on the depression and of serum

prolactin levels among PCOD patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with PCOS diagnosed by the Rotterdam consensus criteria (Presence of 2 of the following 3 conditions: i. amenorrhea /oligomenorrhea ii. clinical or biochemical evidence of hyperandrogenism iii. Polycystic ovaries on ultrasound examination) Mild to moderate major depressive disorder based on DSM-5 criteria Score on Hamilton depression scale <18 Women aged 18-60 years Increased serum level of prolactin (more than 20 ng per dl)

Exclusion criteria:
Psychotic symptoms Presence of any other mental disorder Receiving antidepressant treatment during the last 6 weeks Breastfeeding or pregnancy Thyroid diseases

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Random permuted block

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants, clinicians and outcome raters will be blind regarding grouping

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Keshavarz Blv
City

Tehran
Province
Tehran
Postal code
1417653761
Approval date
2019-10-03, 1398/07/11
Ethics committee reference number
IR.TUMS.VCR.REC.1397.1106

Health conditions studied

1

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

Primary outcomes

1

Description
Severity of depression
Timepoint
Baseline and weeks 4 and 6 after beginning of treatment
Method of measurement
Hamilton Depression Rating Scale 17-Item

2

Description
Serum level of prolactin
Timepoint
Baseline and weeks 4 and 6 after beginning of treatment
Method of measurement
ICMA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: tablet sertraline 100 mg/day as intervention group for 6 weeks
Category
Treatment - Drugs

2

Description
Control group: placebo as control group for 6 weeks
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

psycho somatic clinic-Imam Khomeini Hospital

Full name of responsible person

Prof. Ahmad Ali Noorbala Tafti

Street address

Dr Qharib street, Keshavarz Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2021 to 2026

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

by citing the resource

From where data/document is obtainable

Professor Shahin Akhondzadeh

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

by E mail

Comments