

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Clinical trial to investigate the efficacy of insulin resistance treatment with the metformin in improving mood disorders in patients with polycystic ovarian syndrome

Protocol summary

Summary

The aim of this study is to determine the association between treatments with metformin in insulin resistance polycystic ovarian syndrome (PCOS) patients with mood disorder. In this study, patients with PCOS older than 15 years old randomly selected and after consent are consciously enter our study. The study inclusion criteria: patients with PCOS who meet the Rotterdam criteria; with top 10 score in Anxiety Inventory and top 14 score in the Beck Depression Inventory and Exclusion criteria: patient's consent to continue the study; patients who have been treated PCOS over recent 3 months; patients treated with anxiety disorders and depression; patients with diabetes; Patients with Cushing disease; hyperprolactinemia; congenital adrenal hyperplasia; Patients with serious illnesses and life threatening disease (including cancer, cirrhosis, renal failure; severe heart failure class 3 and 4 serious lung disease) ; pregnancy and lactation. At baseline, insulin resistance using Homa IR will be determined by (fasting plasma insulin×fasting plasma glucose)/22.5 is obtained. Then, in patients who are insulin-resistant (Homa IR index greater than 2.5), mood disorders through questionnaires will be checked. And patients with a score of 14 in the Beck Depression Inventory and score of 10 in the anxiety Beck questionnaire will be chosen and after obtaining informed consent for the study will be selected for 3 months treatment with metformin doses of 1,500 mg. Initiationally metformin is prescribed with 500 mg daily then titrated to 1,500 mg over three weeks and continued up to three months. At the end of three months of treatment, re-evaluate the patient. The insulin resistance by Homa IR and depression and anxiety using the relevant questionnaire will be determined and will be compared results before and after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601106710N6**

Registration date: **2016-03-13, 1394/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-13, 1394/12/23

Registrant information

Name

Mitra Niafar

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

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+98 41 1335 7850

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niafarm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2016-02-19, 1394/11/30

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to investigate the efficacy of insulin resistance treatment with the metformin in improving mood disorders in patients with polycystic ovarian syndrome

Public title

The evaluation of relationship between insulin resistance and mood disorders in patients with polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with PCOS who meet the Rotterdam criteria; with top 10 score in Anxiety Inventory and top 14 score in the Beck Depression Inventory. Exclusion criteria: patient's consent to continue the study; patients who have been treated PCOS over recent 3 months; patients treated with anxiety disorders and depression; patients with diabetes; Patients with Cushing disease; hyperprolactinemia; congenital adrenal hyperplasia; Patients with serious illnesses and life threatening disease (including cancer, cirrhosis, renal failure; severe heart failure class 3 and 4 serious lung disease); pregnancy and lactation.

Age

From **15 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Postal code**Approval date**

2016-01-25, 1394/11/05

Ethics committee reference number

TBZMED.REC.1394.983

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

anxiety and depression scores

Timepoint

Baseline and three months after treatment with metformin

Method of measurement

Based on questionnaire

Secondary outcomes

1

Description

Insulin resistance

Timepoint

Baseline and three months after treatment with metformin

Method of measurement

Test

Intervention groups

1

Description

In all patients, metformin 1500 mg daily for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz, Imam Reza Hospital

Full name of responsible person

Dr.Sevil Gafarzadeh

Street address

Imam Reza Hospital, Gate University, Tabriz, East Azarbaijan

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Vice chancellor for Research of Tabriz University of Medical Sciences,Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

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 of Tabriz 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

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Full name of responsible person

Dr. Mitra Niafar

Position

Endocrinology and Metabolism/ Associate Professor

Other areas of specialty/work

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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