

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

A comparison between clinical, metabolic and endocrine effects of n-acetylcystein and metformin in women with poly cystic ovarian syndrome(PCOS).

Protocol summary

Summary

Objectives: A comparison between clinical, metabolic and endocrine effects of n-acetylcystein and metformin in women with poly cystic ovarian syndrome (PCOS).
Design: Double blind randomized clinical trial. Setting and conduct: The patients will randomly assign into the two groups and will receive treatment for 24 weeks.
Participants: Women with poly cystic ovarian syndrome
Inclusion criteria: 20-36 years old, having poly cystic ovarian syndrome; (Rotterdam society criteria : 2 of 3; having 2 out of 3 criteria including oligo or anovulation, hyperandrogenemia or hyperandrogenism, poly cystic ovaries in ultrasound). **Exclusion criteria:** known other systemic and metabolic disorders, congenital adrenal hyperplasia, Cushing syndrome, androgen producing tumors, hyperprolactinemia, hypo or hyper thyroidism, diabetes mellitus, history of peptic ulcer, and any other drug use. **Intervention:** In one group n-acetylcystein and in the other group metformin will prescribe for 24 weeks.
Main outcome: Change in menstrual cycle, weight, body mass index, fasting blood sugar, serum insulin, low density lipoprotein, HOMA index and high density lipoprotein.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405082624N15**
Registration date: **2014-05-29, 1393/03/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-29, 1393/03/08

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 3487

Email address

maryamka@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-03-16, 1393/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between clinical, metabolic and endocrine effects of n-acetylcystein and metformin in women with poly cystic ovarian syndrome(PCOS).

Public title

Treatment of poly cystic ovarian syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20-36 years old; having poly cystic ovarian syndrome; (Rotterdam society criteria : 2 of 3;

having 2 out of 3 criteria including oligo or anovulation, hyperandrogenemia, or hyperandrogenism, poly cystic ovaries in ultrasound). Exclusion criteria: known other systemic and metabolic disorders; congenital adrenal hyperplasia; Cushing syndrome; androgen producing tumors; hyperprolactinemia; hypo or hyper thyroidism; diabetes mellitus; history of peptic ulcer; any other drug use.

Age

From **20 years** old to **36 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic committee of Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, Ghods Cross.

City

Tehran

Postal code

16117

Approval date

2014-01-26, 1392/11/06

Ethics committee reference number

92/2492 /130/5

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**

change in the menstrual cycle.

Timepoint

Monthly

Method of measurement

Data sheets

Secondary outcomes**1****Description**

change in weight.

Timepoint

24 weeks

Method of measurement

data sheets

2**Description**

change in body mass index.

Timepoint

24 weeks

Method of measurement

data sheets

3**Description**

fasting blood sugar

Timepoint

24 weeks

Method of measurement

data sheets

4**Description**

Serum insulin

Timepoint

24 weeks

Method of measurement

data sheets

5**Description**

change in low density lipoprotein

Timepoint

24 weeks

Method of measurement

data sheets

6

Description

change in HOMA index.

Timepoint

24 weeks

Method of measurement

data sheets

7

Description

change in high density lipoprotein

Timepoint

24 weeks

Method of measurement

data sheets

Intervention groups

1

Description

N- acetylcystein prescription orally, 600 mg 3 times daily (totally 1800 mg), for 24 weeks.

Category

Treatment - Drugs

2

Description

Metformin prescription orally, 500 mg 3 times daily (totally 1500 mg), for 24 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Teaching Hospital

Full name of responsible person

Maryam Kashanian

Street address

Molavi avenue, Molavi Cross.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research ,Iran University of Medical Sciences.

Full name of responsible person

Dr Seyed Javad Mousavi

Street address

Hemmat High way, Chamran Cross.

City

Tehran

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 ,Iran 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

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor.

Other areas of specialty/work

Street address

No 9, Mostaghimi Alley, Khajeh Nasir Toosi Avenue, postcode 16117, Tehran, Iran.

City

Tehran

Postal code

16117

Phone

+98 21 5563 3244

Fax

Email

maryamkashanian@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

MD.

Other areas of specialty/work

Street address

Molavi avenue, Molavi Cross.

City

Tehran

Postal code

16117

Phone

+98 21 5563 3244

Fax

Email

maryamkashanian@yahoo.com

Web page address

Phone

+98 21 5563 3244

Fax

Email

maryamkashanian@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor

Other areas of specialty/work

Street address

Molavi Avenue, Molavi Cross.

City

Tehran

Postal code

16117

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