

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of the effect of exercise on anthropometric status, some metabolic and inflammatory profiles of women with polycystic ovary syndrome.

Protocol summary

Study aim

Evaluation of the effect of exercise training on anthropometric status, some metabolic, inflammatory and oxidative stress profiles of women with polycystic ovary syndrome.

Design

This study is an open-label clinical trial. The study population will be all women with polycystic ovary syndrome referred to Imam Reza hospital of Kermanshah. 90 eligible patients will be selected conveniently and randomly assigned to 3 intervention and control groups (2 intervention groups and one control group).

Settings and conduct

This study that will be conducted in Imam Reza hospital of Kermanshah is a double-blind one that , researchers and data analysts were kept blind to the allocation of study groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome; Age between 18 to 40 years Exclusion criteria: Taking oral contraceptives; Taking hormone drugs affecting total testosterone levels over the past three months

Intervention groups

The first intervention group will receive alternative training with 50 to 110 percent maximum aerobic velocity (MAV) three times a week for 8 weeks with a treadmill. The second intervention group will receive combination of aerobic and resistance training with 50% to 70% 1RM and 50% to 70% maximum heartbeat rate (MHR) three times a week for 8 weeks. The control group will receive no intervention.

Main outcome variables

Lipid profile; Fasting blood Glucose; Insulin; Insulin resistance (HOMA-IR), Maximum oxygen consumption ($\dot{V}O_2$ max)

General information

Reason for update

Change in proposal

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N143**

Registration date: **2020-03-22, 1399/01/03**

Registration timing: **prospective**

Last update: **2022-10-23, 1401/08/01**

Update count: **2**

Registration date

2020-03-22, 1399/01/03

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-02, 1399/01/14

Expected recruitment end date

2020-10-05, 1399/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of exercise on anthropometric status, some metabolic and inflammatory profiles of women with polycystic ovary syndrome.

Public title

Evaluation of the effect of exercise on women with polycystic ovary syndrome status.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with polycystic ovary syndrome Age between 18 to 40 years

Exclusion criteria:

Taking oral contraceptives Taking hormone drugs affecting total testosterone levels over the past three months

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

"Randomization was done from a computer-generated sequence(random number generator software), concealed in sequentially numbered, sealed, opaque envelopes(SNOSE method), and kept by the Clinic technician of the two centres."

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 Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for

Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-02-03, 1398/11/14

Ethics committee reference number

ir.kums.rec.1398.1186

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**

Insulin resistance

Timepoint

Beginning and end of the study (after 8 weeks)

Method of measurement

Standard formula

2**Description**

Maximum oxygen consumption ($\dot{V}O_2$ max)

Timepoint

Beginning and end of the study (after 8 weeks)

Method of measurement

Standard formula

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group, will receive alternative training with 50 to 110 percent maximum aerobic velocity (MAV) three times a week for 8 weeks with a treadmill.

Category

Treatment - Other

2

Description

The second intervention group will receive a combination of aerobic and resistance training with 50% to 70% 1RM and 50% to 70% maximum heartbeat rate (MHR) three times a week for 8 weeks.

Category

Treatment - Other

3

Description

The control group will receive no intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Solmaz Alavi Milani

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

s.alavimilani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

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6715847141

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+98 83 3836 0014

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fnajafi@kums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Solmaz Alavi Milani

Position

Member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

Send E-mail to the responsible for the update to get the documentation

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

Documentation will be emailed within a 15-day timeframe

Comments