Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of effects of diet and exercise program to improve clinical symptoms and laboratory tests in obese women with polycystic ovary syndrome (PCOS)

Protocol summary

Summary

The aim of the study to determine the effect of diet and exercise program to improve clinical symptoms and laboratory tests of polycystic ovary syndrome women are obese. This study is randomized controlled trial and several Central. Main criteria for inclusion are being overweight, having oligomenorrhea and hirsutism. The main criteria for exclusion are having any acute or chronic medical illnesses, having diet or exercise program before the start of the study. Sample size is 50 people (25 people in experiment group and 25 people in control group). In baseline demographic data of all patients (weight, height and body mass index) and menstrual status (having or not having oligomenorrhea) and clinical characteristics of hyprandrogenisim such as hirsutism, acne, alopecia and biochemical and hormonal assessment such as fasting blood suger, Triglycerides, Cholesterol, Urea, Creatinine, complete blood cells count, Cortisol, Prolactin, total and free Testosterone levels, Estradiol, 17 Hydroxy Progesterone, Dehydroepiandrosterone Sulphate, sex hormone binding globulin, follicular stimulating hormone and Luteinized hormone will be assessed. Also abdominal ultrasound for finding of radiological characteristics of polycystic ovary syndrome for all participants will be done. Intervention plan including exercise and diet program for exprimental group run for 12 weeks and then all of these assessments within three months after the study in both groups will be repeated again. Intervention time will begin at January 2010. Evaluation of patients (for using drugs and doing diet and exercise completely) will be done by the Executive and colleagues in the study weekly.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104032892N1**
Registration date: **2011-04-03, 1390/01/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-04-03, 1390/01/14

Registrant information

Name

Mani Mirfeizi

Name of organization / entity

Islamic Azad University Karaj branch

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Islamic Azad University of karaj branch

Expected recruitment start date

2010-01-15, 1388/10/25

Expected recruitment end date

2011-07-16, 1390/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of effects of diet and exercise program to improve clinical symptoms and laboratory tests in obese women with polycystic ovary syndrome (PCOS)

Public title
Effect of diet and exercise program to improve polycystic ovary syndrome (PCOS)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1- Participants have body mass index≥ 25 kg/ m2; 2- All Participants treat with same dose of oral contraceptives pill and spirnolacton; 3- All Participants have menstrual pattern as oligomenorrhea (irregular bleeding episodes with intervals occur more than 35 days); 4- All Participants have suffered some degree of hirsutism. Exclusion criteria: 1- Use of any drug other than the standard drug for the treatment of polycystic ovary syndrome, which is the same for everyone. (Including drugs to treat infertility, diabetes, hormonal drugs, reduce appetite and etc); 2- Smoking; 3- Being in pregnancy and lactation period or pregnancy decision; 4- Having cardiovascular, renal, liver, respiratory diseases, diabetes, uncontrolled hypertension, malignancy or any other acute or chronic disease; 5- Prohibition of the exercise due to illness or any other cause according to physician order; 6- Participating in regular exercise before the start of the study; 7- Having a separate diet programs before the start of the study.

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Islamic Azad university Karj barnch

Street address
Crossroad of Moazen Blv and Esteghlal Blv, Rajaeeshahr, Karaj, Mailbox: 31485-313

City
Karaj

Postal code

Approval date
2010-07-18, 1389/04/27

Ethics committee reference number
002

Health conditions studied

1

Description of health condition studied
polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Endocrine, nutritional and metabolic diseases(E00-E90)

Primary outcomes

1

Description
Serum testosterone(total & free)

Timepoint
Before intervention - three months after intervention

Method of measurement
Serological test with Electro Komolomynsans method with using of the company's ROCHE kits

2

Description
serum Dehydroepiandrosterone Sulphate (DHEAS)

Timepoint
Before intervention - three months after intervention

Method of measurement
Serological test with Electro Komolomynsans method with using of the company's ROCHE kits

3

Description
Serum sex hormone binding globulin (SHBG)

Timepoint
Before intervention - three months after intervention

Method of measurement
Serological test with Electro Komolomynsans method with using of the company's ROCHE kits

4

Description
Body mass index(BMI)

Timepoint
Before intervention - three months after intervention

Method of measurement
By measuring the height (m) and weight (kg)

5

Description
hirsutism
Timepoint
Before intervention - three months after intervention
Method of measurement
Using Friedman and Galway scale

6

Description
oligomenorrhea
Timepoint
Before intervention - three months after intervention
Method of measurement
Considering the menstrual cycle (irregular bleeding episodes with intervals of more than 35 days)

7

Description
ovary status
Timepoint
Before intervention - three months after intervention
Method of measurement
using abdominal ultrasound

Secondary outcomes

1

Description
serum Progestron
Timepoint
Before intervention - three months after intervention
Method of measurement
Serological test with Electro Komolomynsans method with using of the company's ROCHE kits

2

Description
Serum LH
Timepoint
Before intervention - three months after intervention
Method of measurement
Serological test with Electro Komolomynsans method with using of the company's ROCHE kits

3

Description
serum FSH
Timepoint
Before intervention - three months after intervention
Method of measurement
Serological test with Electro Komolomynsans method with using of the company's ROCHE kits

4

Description
serum stradiol
Timepoint
Before intervention - three months after intervention
Method of measurement
Serological test with Electro Komolomynsans method with using of the company's ROCHE kits

5

Description
serum prolactin
Timepoint
Before intervention - three months after intervention
Method of measurement
Serological test with Electro Komolomynsans method with using of the company's ROCHE kits

6

Description
serum T3
Timepoint
Before intervention - three months after intervention
Method of measurement
Serological test with Electro Komolomynsans method with using of the company's ROCHE kits

7

Description
serum T4
Timepoint
Before intervention - three months after intervention
Method of measurement
Serological test with Electro Komolomynsans method with using of the company's ROCHE kits

8

Description
serum TSH
Timepoint
Before intervention - three months after intervention
Method of measurement
Serological test with Electro Komolomynsans method with using of the company's ROCHE kits

Intervention groups

1

Description
Experimental group: Diet and exercise program Diet plan: at the beginning of study a check list prepared for each individual and weekly regimen recommended separately based on feeding patterns and individual facilities. The method of regimen calculation based on total energy for each individual (TEE). We set the countable energy for reducing weight 1000 grams per week. Reduced the amount of energy and some energy

into the physical activity to lose weight fraction are obtained. The combination of energy, including 40% carbohydrate, 30% fat (less than 8% saturated fatty acids was) and 30% protein is high physiological value. Fitness program: exercise sessions that included 24 meeting which duration per session was variable according to the program. For improving aerobic energy system and strengthen cardiovascular system a series exercises (slow jogging) will be used. At the beginning of the first practice sessions will be used slow intensity aerobic exercise. The first training sessions with 5 minutes of times, and 50 percent of maximum heart rate of cholera in the form alternating between resting half the time repeating the exercise. In each session we were trying to follow the principle of overload for improving cardiovascular efficiency. In higher stages (after the fifth session) of the repetition of exercises with some 60 percent of maximum heart rate is achieved. Of the ninth session, training intensity reaches to 70 percent of maximum heart rate and in last sessions with 80 percent maximum heart rate do their exercise. In each session, subjects in the first 10 minutes to warm the body and also the final 10 minutes of cooling down exercises and return to the initial state.

Category

Lifestyle

2

Description

For controls group: The standard drugs Diane: from fifth Day of cycle for 21 days every night, once a day Spironolactone: 25 mg twice a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology Clinic of Dr. Mani Mirfeizi

Full name of responsible person

Dr. Mani Mirfeizi

Street address

Omid physicians clinic, Beheshti Avenue, Karaj

City

Karaj

2

Recruitment center

Name of recruitment center

Private clinic of Dr. Sousan Kiani

Full name of responsible person

Dr. Sousan Kiani

Street address

Nilufar physicians clinic, Beheshti Avenue, Karaj

City

Karaj

3

Recruitment center

Name of recruitment center

Studies and Researches Center for Sport Sciences, Islamic Azad University of Karaj

Full name of responsible person

Dr. Shahla Hojat

Street address

Next Sabzeh Parvar Clinic, Takhti Ave, Yadegar Emam Street, Azadegan Square, Karaj

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Islamic Azad University of karaj branch

Full name of responsible person

Dr. Abas Ahmadi

Street address

Vice chancellor for research, Islamic Azad University of karaj branch, Crossroad of Moazen Blv and Esteghlal Blv, Rajaeeshahr, Karaj

City

Karaj

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, Islamic Azad University of karaj branch

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

Islamic Azad University Karaj branch

Full name of responsible person

Dr. Mani Mirfeizi

Position

Professor of Internal medicine / Head of Nursing and Midwifery Karaj branch

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