

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### An evaluation of the efficacy of a "Home Base Exercise" program in clinical signs and hormonal and metabolic profile in patients with Poly Cystic Ovarian Syndrome (PCOS); a Randomized Clinical Trial

#### Protocol summary

##### Summary

The purpose of this study was to evaluate the effects of a "Home Base Exercise" plan on metabolic and hormonal parameters in patients with PCOs. Forty PCO patients of Gynecologic or Endocrinologic clinic were assigned to intervention or control group based on a block randomization method. A "Home Base Exercise" plan including 30 minutes of aerobic and resistive exercises 3 times a week was given to patients in the intervention group; and no exercise program to the control group. In both group, the routine treatments (according to Gynecologic or Endocrinologic clinic) and regular diet were continued and they were followed for 3 months. Age, Weight, Body Mass Index (BMI), Blood Pressure, Abdominal Circumference and Abdominal: gluteal circumference ratio was measured at the beginning of the study. Serum concentration of TSH, Prolactin, 17-Hydroxy Progesterone (17-OHP), Testosterone, FBS, Insulin, TG, Cholesterol, HDLc, and hsCRP were measured at the beginning of the study and at the end of the 3 month period of exercise program.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138902073819N1**  
Registration date: **2009-12-15, 1388/09/24**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2009-12-15, 1388/09/24

##### Registrant information

Name

Shahrzad Khosravi

##### Name of organization / entity

Sport medicine Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8863 0227

##### Email address

sh\_khosravi@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2009-12-15, 1388/09/24

##### Expected recruitment end date

2010-06-15, 1389/03/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

An evaluation of the efficacy of a "Home Base Exercise" program in clinical signs and hormonal and metabolic profile in patients with Poly Cystic Ovarian Syndrome (PCOS); a Randomized Clinical Trial

##### Public title

An evaluation of the efficacy of a "Home Base Exercise" program in clinical signs and hormonal and metabolic profile in patients with Poly Cystic Ovarian Syndrome (PCOS); a Randomized Clinical Trial

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Definite diagnosis of poly cystic ovary  
Exclusion criteria: BMI>35kg/m2, Cancer, Metabolic Diseases (FBS>126mg/dl, Endocrine diseases, Hepatic, renal or cardiovascular diseases, Drugs (OCP, Glucocorticoids, Anti-androgens, Anti-Diabetics), Cigarette smoking, Alcohol consumption, pregnancy and failure to follow-up

#### Age

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

#### Gender

Female

#### Phase

1

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **20**

#### 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

Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences

##### City

Tehran

##### Postal code

#### Approval date

2007-02-01, 1385/11/12

#### Ethics committee reference number

87-04-53-8006

## Health conditions studied

### 1

#### Description of health condition studied

Polycystic ovary syndrome

#### ICD-10 code

E28.2

#### ICD-10 code description

Sclerocystic ovary syndrome Stein-Leventhal syndrome

## Primary outcomes

### 1

#### Description

17(oh)Progesteron

#### Timepoint

before and 3 month after intervention

#### Method of measurement

radioimmunoassays (RIA)

### 2

#### Description

change in weight

#### Timepoint

before and 3 month after intervention

#### Method of measurement

weight calculator

### 3

#### Description

BMI

#### Timepoint

before and 3 month after intervention

#### Method of measurement

weight/height\* height

### 4

#### Description

waist to hip ratio

#### Timepoint

before and 3 month after intervention

#### Method of measurement

waist to hip ratio

### 5

#### Description

Blood pressure

#### Timepoint

before and 3 month after intervention

#### Method of measurement

BP calculator

### 6

#### Description

Prolactin

#### Timepoint

before and 3 month after intervention

#### Method of measurement

radioimmuno assay

### 7

#### Description

TG

#### Timepoint

before and 3 month after intervention

#### Method of measurement

commercial kits

## **8**

### **Description**

FBS

### **Timepoint**

before and 3 month after intervention

### **Method of measurement**

Glucose oxidase method

## **9**

### **Description**

Insulin

### **Timepoint**

before intervention, 3 month

### **Method of measurement**

immunoassay enzyme

## **10**

### **Description**

Insulin resistance

### **Timepoint**

before and 3 month after intervention

### **Method of measurement**

FBS/Insulin

## **11**

### **Description**

HDL

### **Timepoint**

before and 3 month after intervention

### **Method of measurement**

commercial kits

## **12**

### **Description**

Testosterone

### **Timepoint**

before and 3 month after intervention

### **Method of measurement**

radioimmunoassays (RIA)

## **13**

### **Description**

TSH

### **Timepoint**

before and 3 month after intervention

### **Method of measurement**

radioimmunoassays (RIA)

## **14**

### **Description**

Cholesterol

### **Timepoint**

before and 3 month after intervention

### **Method of measurement**

commercial kits

## **15**

### **Description**

hsCRP

### **Timepoint**

before and 3 month after intervention

### **Method of measurement**

commercial kits

## **Secondary outcomes**

### **1**

#### **Description**

Cardiovascular effect

#### **Timepoint**

before intervention and 3 months after intervention

#### **Method of measurement**

hsCRP

## **Intervention groups**

### **1**

#### **Description**

Home Base Exercise program / Aerobic (at least 5 days, 30 minutes each) and Resistance exercise (3 days), for 3 months

#### **Category**

Lifestyle

### **2**

#### **Description**

No exercise in control group, general consultation only

#### **Category**

Behavior

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Vali e asr reproductive health research center, Imam khomainsi hospital

##### **Full name of responsible person**

Dr. Shahrzad Khosravi

##### **Street address**

Imam Khomainsi hospital, Tehran, Iran,

##### **City**

Tehran

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Dr. Vasheghani Farahani

**Street address**

Vice Chancellery For Research, Tehran University of Medical Sciences, Hezarjarib Boulevard, Isfahan, Iran.

**City**

Tehran

**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**

*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**

Tehran University of Medical Sciences

**Full name of responsible person**

Shahrazad Khosravi

**Position**

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**Web page address****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*