

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The effect of high-fiber, low-calorie balanced diet on some factors in obese or overweight hirsute women with pco

#### Protocol summary

##### Summary

Object of This study is investigate the effect of low calorie high fiber diet on some factors in obese or overweight hirsute women and Pco . This study is based on a not blind randomized clinical trial that perform on 50 hirsute women with this inclusion criteria ( Hirsutism or Pco confirmed by a physician; lack of food or certain medications; lack of gastrointestinal disease; hepatic, metabolic, cardiovascular, renal,...; women ages 18-45; not pregnant; not lactating; non-smoking; non-hormonal drugs in the past three months; patients treated with the same way). The population of eligible women is divided into two groups, A and B, each of which consists of 25 patients using Randomized block permutation. Women are well aware that they are divided randomly In an intervention or control group. The 24-hour dietary recall questionnaire and demographic information completed by researcher. 10 cc blood sample will be taken for the measurement of total lipid, cholesterol, triglycerid, insulin, prolactin, FBS on days 3-5 of the menstrual period, Before and one month after the completion of intervention .Time of the intervention is 3 month and The intervention including the use of high-fiber and low-calorie diet or a normal diet . During the intervention, the researcher follow the people by telephone or person visit And the results of study will be analyzed . Exclusion criteria: medical problems during the study; unwillingness to cooperate; pregnancy; Gastrointestinal problems when using a high-fiber diet

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014101918187N3**

Registration date: **2014-12-07, 1393/09/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-12-07, 1393/09/16

##### Registrant information

###### Name

Sedighe Forouhari

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 987136474257

###### Email address

foruharis@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Shiraz University of Medical Sciences

##### Expected recruitment start date

2014-11-22, 1393/09/01

##### Expected recruitment end date

2015-01-21, 1393/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of high-fiber, low-calorie balanced diet on some factors in obese or overweight hirsute women with pco

##### Public title

The effect of high -fiber diet on hirsutism and Pco

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Hirsutism or Pco confirmed by a physician; lack of food or certain medications; lack of gastrointestinal disease, hepatic, metabolic, cardiovascular, renal, women ages 18-45; not pregnant; not lactating; non-smoking; non-hormonal drugs in the past three months; patients treated with the same way; exclusion criteria: medical problems during the study; unwillingness to cooperate; pregnancy; gasterointestinal problems when using a high-fiber diet

### **Age**

From **18 years** old to **45 years** old

### **Gender**

Female

### **Phase**

3

### **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**

Randomization by block permutation

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Shiraz University Of Medical Sciences, vice chancellor for research of Shiraz Un

##### **Street address**

Zand street , Shiraz , central building of Shiraz University of Medical Sciences

##### **City**

Shiraz

##### **Postal code**

71345-1978

#### **Approval date**

2014-09-28, 1393/07/06

#### **Ethics committee reference number**

7751-9371

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Hirsutism

#### **ICD-10 code**

L68.0

#### **ICD-10 code description**

Hirsutism

### 2

#### **Description of health condition studied**

poly cystic ovarian syndrom

#### **ICD-10 code**

E28.2

#### **ICD-10 code description**

poly cystic ovarian syndrom

## **Primary outcomes**

### 1

#### **Description**

Total Lipid

#### **Timepoint**

before the intervention and one month after the completion of intervention

#### **Method of measurement**

laboratory

### 2

#### **Description**

cholesterol

#### **Timepoint**

Before the intervention and one month after the completion of intervention

#### **Method of measurement**

Lab data

### 3

#### **Description**

Triglycerid

#### **Timepoint**

Before the intervention and one month after the completion of intervention

#### **Method of measurement**

Lab data

### 4

#### **Description**

Insulin

#### **Timepoint**

Before the intervention and one month after the completion of intervention

#### **Method of measurement**

Lab data

### 5

#### **Description**

prolactin

**Timepoint**

Before the intervention and one month after the completion of intervention

**Method of measurement**

Lab data

**6**

**Description**

FBS

**Timepoint**

Before the intervention and one month after the completion of intervention

**Method of measurement**

Lab data

**Secondary outcomes**

**1**

**Description**

Body mass index

**Timepoint**

Before the intervention and one month after the completion of intervention

**Method of measurement**

Kg/m2

**Intervention groups**

**1**

**Description**

intervention group : high-fiber, low-caloric balance diet ,for 3 month The list of high fiber diet have been give to people

**Category**

Lifestyle

**2**

**Description**

Control group(normal diet without any changing ,for 3 month)

**Category**

Lifestyle

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid motahari clinic

**Full name of responsible person**

korouni Atefe, Studend of Msc in Midwifery

**Street address**

Namazi square, Zand street , Shiraz

**City**

Shiraz

**2**

**Recruitment center**

**Name of recruitment center**

Shahid Faghihi clinic

**Full name of responsible person**

korouni Atefe, Studend of Msc in Midwifery

**Street address**

adjucent to University of Medical Sciences, Zand street, Shiraz

**City**

Shiraz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research of Shiraz University Of Medical Science

**Full name of responsible person**

Dr Seyed Basir Hashemi

**Street address**

Shiraz University of Medical Sciences ,Zand Street, Shiraz

**City**

Shiraz

**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 Shiraz University Of Medical Science

**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Sedighe Forouhari

**Position**

Master of Midwifery

**Other areas of specialty/work**

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**Full name of responsible person**

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authority of infertility research center

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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*