

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of high-fiber, low-calorie balanced diet on some hirsutism related hormones level in obese or overweight hirsute women

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 free testosterone , DHEA-S , SHBG, androstendion ,17OHP, LH , FSH 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: **IRCT2014102119624N1**

Registration date: **2014-12-08, 1393/09/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-08, 1393/09/17

Registrant information

Name

Atefe Korouni

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 5387 2421

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stud2550071271@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Central building of Shiraz University of Medical Sciences, Dr. Seyed Basir Hashemi, Zand street, Shiraz

Expected recruitment start date

2014-11-11, 1393/08/20

Expected recruitment end date

2015-02-09, 1393/11/20

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 hirsutism related hormones level in obese or overweight hirsute women

Public title

The effect of high -fiber, low- calorie diet on hirsutism

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; BMI \geq 25 Exclusion criteria: medical problems during the study; unwillingness to cooperate; pregnancy; problems arise 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 using block permutation

Secondary Ids

empty

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

Ethics Committee,Vice chancellor for research , Shiraz University of Medical Sciences

Street address

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

City

Shiraz

Postal code

1978-71345

Approval date

2014-10-27, 1393/08/05

Ethics committee reference number

ct-9376-7186

Health conditions studied**1****Description of health condition studied**

Hirsutism

ICD-10 code

L68.0

ICD-10 code description

Hirsutism

Primary outcomes**1****Description**

Free Testosterone

Timepoint

Before the intervention and one month after the completion of intervention

Method of measurement

Lab data

2**Description**

Dehydroepiandrosterone sulphate

Timepoint

Before the intervention and one month after the completion of intervention

Method of measurement

Lab data

3**Description**

Sex Hormone Binding Globulin

Timepoint

Before the intervention and one month after the completion of intervention

Method of measurement

Lab data

4**Description**

Anderestendion

Timepoint

Before the intervention and one month after the completion of intervention

Method of measurement

Lab data

5**Description**

17-Hydroxyprogesterone

Timepoint

Before the intervention and one month after the completion of intervention

Method of measurement

Lab data

6

Description

Luteinizing Hormone

Timepoint

Before the intervention and one month after the completion of intervention

Method of measurement

Lab data

7

Description

Follicle Stimulating Hormone

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, the list of high fiber diet have been give to people ,for 3 month)

Category

Lifestyle

2

Description

Control group(normal diet ,for 3 month, Without any change in diet)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi hospital, Shiraz

Full name of responsible person

korouni Atefe , Studend of Msc in Midwifery

Street address

Adjucent to the University of Medical Sciences , Zand

street , Shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Shahid Motahari clinic

Full name of responsible person

korouni Atefe , Studend of Msc in Midwifery

Street address

Cercle of Namazi , Zand street , Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for reaserch of Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Technology and Research Office,vice chancellor for reaserch , Central Building of Shiraz University of Medical Science, 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 reaserch of Shiraz 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

Shiraze university of medical sciences

Full name of responsible person

Sedighe Forouhari

Position

Master of Midwifery/ Guide Master

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