Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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, anderestendion ,17OHP, LH , FSH On days 3-5 of the menst ural period, Befor 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
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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≥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
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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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Person responsible for scientific inquiries

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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