Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of oral thylakoid intake on the metabolic, hormonal and inflammatory parameters in obese women with polycystic ovary syndrome under hypocaloric diet: A randomized double-blinded placebo controlled trial

Protocol summary

Study aim

The aim of the present study is to investigate the effects of oral intake of thylakoid with low calorie diet on the metabolic, hormonal and inflammatory factors in obese women with polycystic ovary syndrome.

Design

Randomized double-blind clinical trial with two arm parallel groups

Settings and conduct

The study will be conducted in the Tabriz University of Medical Sciences associated clinics, and supplementation duration will be 12 weeks.The thylakoid and placebo sachets will be coded by the person responsible for preparing them, and the main investigators and the patients will be blinded to the type of the supplement each group receives.

Participants/Inclusion and exclusion criteria

48 women with polycystic ovary syndrome with BMI of 30-40 Kg/m2 will be included in the study. Pregnancy, lactation, and co-morbidity of other metabolic diseases are among the exclusion criteria of the study.

Intervention groups

The Individuals in both groups will receive a low-calorie diet considering their dietary habits. Patients in the thylakoid group will take a 5 gram thylakoid sachet with their lunch, daily. In the placebo group, the sachet will contain 5 grams of raw corn starch.

Main outcome variables

Anthropometric indices, body composition, insulin resistance index (HOMA-IR), components of metabolic syndrome, serum levels of free fatty acid, omentin, chemerin, hs-CRP, Neoptrin, FSH, LH, testosterone, SHBG and free androgen index(FAI).

General information

Reason for update

In order to need a precise interpretation of the mechanism of action of thylakoid in terms of metabolic, inflammatory, and hormonal effects in the study subjects, the measurement and evaluation of serum levels of these newly added parameters were considered necessary.

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20140907019082N9**
Registration date: **2018-09-23, 1397/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-01, 1399/11/13**
Update count: **1**

Registration date

2018-09-23, 1397/07/01

Registrant information

Name

Mahdieh Abbasalizad Farhangi

Name of organization / entity

Department of Community Nutrition School of Nutrition

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-08-29, 1397/06/07
Expected recruitment end date
2018-12-21, 1397/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of oral thylakoid intake on the metabolic, hormonal and inflammatory parameters in obese women with polycystic ovary syndrome under hypocaloric diet: A randomized double-blinded placebo controlled trial

Public title
Effect of oral thylakoid intake with low-calorie diet in the treatment of polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients in our selected population were diagnosed with polycystic ovary syndrome according to Rotterdam diagnostic criteria with the diagnosis of the gynecologist.Having at least two of the three following symptoms:1-Abnormal menstrual cycles (oligomenorrhea, amenorrhea)2- Polycystic ovary in ultrasound3- Clinical signs of hyperandrogenism (Acne-Hirsutism) or biochemical symptoms of hyperandrogenism. Women aged 20-40 years Body Mass Index (BMI) range: 30-40 Kg/m2 Moderate activity level Only OCP consumer (estrogen and progesterone combination pills). All participants will only receive OCP. Willingness to participate in the study
Exclusion criteria:
Pregnancy(tendency to become pregnant) or lactation Having any illness that affecting the studied variables (such as liver disease, thyroid disease, cardiovascular disease, renal disease, gastrointestinal disease , Cushing's syndrome,adrenal hyperplasia, androgen-secreting tumors , hyperprolactinemia). Insulin infusion and intakes of blood pressure regulating drugs, statins and or drugs that affect insulin resistance (such as metformin), thiazolidinedione, anti androgens. Using of any vitamin and mineral supplements and or antioxidants or being under certain diets at least two months before the study. Any changes in the therapeutic protocol during the study
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
From among the patients who volunteer to participate in the study, 48 individuals will be selected by simple randomization. Then by using the Random Allocation Software, the subjects will be allocated into either thylakoid or placebo group, stratified by age and body mass index (BMI).
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the main investigators (including the student, and her supervisor and adviser professors) as well as the patients will be blinded to the type of the supplement (thylakoid or placebo) received by each group. The person responsible for preparing the supplement sachets (who is completely unrelated to the study) will be asked to assign a three digit code to each of the two powders (prebiotic and placebo), and keep the codes for himself until the end of the study and data analyses.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Research Ethics Committee of Tabriz University of Medical Sciences
Street address
Research & Technology Dept, Third Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golghast St.
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Tabriz
Province
East Azarbaijan
Postal code
516614711
Approval date
2018-08-27, 1397/06/05
Ethics committee reference number
IR.TBZMED.REC.1397.447

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Anthropometric indices
Timepoint
Baseline, middle of the study(sixth week) and 12 weeks after intervention
Method of measurement
Seca Scale, stadiometer and strip meter

2

Description
Body composition
Timepoint
Baseline, middle of the study(sixth week) and 12 weeks after intervention
Method of measurement
With the body composition analyzer

3

Description
Lipid profile
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Laboratory evaluation

4

Description
Fasting Blood Glucose (FBG)
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Laboratory evaluation

5

Description
Serum level of Insulin
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELIZA

6

Description
Insulin resistance index
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Using formula

7

Description
Serum levels of free fatty acid (FFA)
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELIZA

8

Description
Systolic and diastolic blood pressure
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
manometer

9

Description
Serum level of chemerin
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELIZA

10

Description
Serum level of Omentin
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELIZA

11

Description
Inflammatory factors
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELIZA

12

Description
Serum levels of testosterone
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELIZA

13

Description
Serum levels of sex hormone binding glubolin (SHBG)
Timepoint
Baseline and 12 weeks after intervention

Method of measurement
ELIZA

14

Description
Serum levels of LH
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELIZA

15

Description
Serum levels of FSH
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELIZA

16

Description
Serum levels of DHEA-s
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELIZA

Secondary outcomes

1

Description
serumic Sirtuin- 1
Timepoint
before and after of study
Method of measurement
ELISA

2

Description
Renal function parameters (serum levels of albumin, total protein, creatinine and blood urea nitrogen)
Timepoint
before and after of study
Method of measurement
Bromocresol Green(for Albumin), Creatinine (jaffe), others(colorimetric)

3

Description
TAC (total antioxidant capacity)
Timepoint
before and after of study
Method of measurement
Colorimetry (by spectrophotometry)

4

Description
Catalase
Timepoint
before and after of study
Method of measurement
Colorimetry (by spectrophotometry)

5

Description
MDA
Timepoint
before and after of study
Method of measurement
Colorimetry (by spectrophotometry)

6

Description
serum LPS
Timepoint
before and after of study
Method of measurement
ELISA

7

Description
serum Brain-Derived Neurotrophic Factor (BDNF)
Timepoint
before and after of study
Method of measurement
ELISA

8

Description
Serumic S100B
Timepoint
before and after of study
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: Patients in this group will receive low-calorie diet with a thylakoid supplement for 12 weeks. Thylakoid supplement is a sachet containing 5 grams of thylakoid (extracted from spinach leaves and made by a researcher) which will be dissolved in a glass of water and used once a day with lunch.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group will receive low-

calorie diet and placebo for 12 weeks. Placebo is a sachet containing 5 grams of raw corn starch, which will be dissolved in a glass of water and used once a day with lunch.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital affiliated to Tabriz University of Medical Sciences

Full name of responsible person

Dr. Maryam Vaezi

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Alzahra Hospital, Artesh Ave, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Tabriz University of Medical Sciences,

Full name of responsible person

Dr Abolghasem Jouyban

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Research & Technology Dept,Third Floor,Tabriz University of Medical Sciences Central building No. 2, Gulgasht St

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Web page address

https://researchvice.tbzmed.ac.ir

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 , Tabriz University of Medical Sciences,

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Pourteymour Fard Tabrizi

Position

Ph.D. candidate in Nutritional Sciences

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Mahdieh Abbasalizad Farhangi

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Associate Professor of Nutrition Sciences

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Ph.D. Candidate in Nutrition Sciences

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable