

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Oct 2021

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

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Name of organization / entity

Department of Community Nutrition School of Nutrition

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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 ultrasound 3- 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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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 globulin (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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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

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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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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