Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Study of the effect of canola and olive oils consumption on anthropometric, inflammatory, glycemic and hormonal indices, lipid profiles, grade of fatty liver and mood disorder score in patients with polycystic ovary syndrome

Protocol summary

Study aim
Determination of the effects of canola and olive oil on anthropometric and inflammatory indices, glycemic and hormone indices, lipid profile, fatty liver grade and mood disturbance in patients with PCOS.

Design
The present study is a randomized double-blind clinical trial with control group on patients with PCOS.

Settings and conduct
90 samples were divided into three groups receiving 25 grams/day of Canola oil, 25 grams/day of olive oil and 25 grams/day of sunflower oil, using a randomized permuted block method. every groups recieved diet using adjusted ideal body weight. Macronutrient distribution in diet will be given in the form of 65-45% CHO, 10-15% Pr and 30-35% fat, and replace the calculated fat content with intervention and control oils.In this study,there are 3 visits for the patient at the beginning, week 5 and the end of the study. The intervention and control oils are given at a monthly rate with 25 grams modulus. This study was conducted in the form of double-blind that patients and physicians and investigators be unaware of the type of intervention that they were taking.

Participants/Inclusion and exclusion criteria
Inclusion criteria: -People with PCOS/18 to 45 years/overweight or obesity. -no use of any drug and / or surgical treatment -Not having any systemic disease and other endocrine disorders -Lack of Pregnancy and Breastfeeding Exclusion criteria: -Start taking or any dose changes in medications -Get pregnancy -Acceptance of less than 80% of the intervention

Intervention groups
In this study, two groups receiving 25 grams/day of canola oil and 25 grams/day of olive oil as intervention groups and one group receiving 25 grams/day of sunflower oil as a control group.

Main outcome variables
Effects of canola and olive oil on anthropometric indices, inflammatory indices, glycemic and hormonal indices, lipid profile, lipid profile and mood disturbance in patients with PCOS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190407043193N1**
Registration date: **2019-06-30, 1398/04/09**
Registration timing: **retrospective**

Last update: **2019-06-30, 1398/04/09**
Update count: **0**

Registration date
2019-06-30, 1398/04/09

Registrant information

Name
Maryam Yahay

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2018-10-22, 1397/07/30

Expected recruitment end date

2019-03-15, 1397/12/24

Actual recruitment start date

2018-10-22, 1397/07/30

Actual recruitment end date

2019-03-15, 1397/12/24

Trial completion date

2019-03-17, 1397/12/26

Scientific title

Study of the effect of canola and olive oils consumption on anthropometric, inflammatory, glycemic and hormonal indices, lipid profiles, grade of fatty liver and mood disorder score in patients with polycystic ovary syndrome

Public title

effect of canola and olive oils consumption in polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The definitive diagnosis of PCOS based on diagnostic criteria (Rotterdam3) by the physician The absence of other endocrine disorders or the conditions that lead to some or most of the clinical manifestations and disorders associated with PCOS (such as congenital or non-classic adrenal hyperplasia, Cushing's syndrome, androgens secreting tumors, drugs induced hyperandrogenism, idiopathic hyperandrogenism, hirsutism Idiopathic, thyroid dysfunction, hyperprolactinemia, pregnancy, lactation and menopause) Non-use of any drug and / or surgical treatment for the clinical symptoms and disorders associated with PCOS other than OCP (such as spironolactone, finasteride, isotretinoin, letrozole, clomiphene, gonadotropins, metformin, cyproterone, rosiglitazone, pioglitazone, ovarian laparoscopic surgery, and Auxiliary reproductive technology) Absence of any severe or significant systemic disease requiring treatment such as any cancer; digestive, liver or endocrine disorders (such as celiac disease, Crohn's disease, ulcerative colitis), diabetes mellitus, hyperparathyroidism, hypercalcemia, or hyperphosphatemia); cardiovascular disorders (e.g. Uncontrolled hypertension or history of myocardial infarction); kidney disorders (such as renal failure, nephrotic syndrome); blood coagulation disorders (eg thalassemia, hemophilia); neurological disorders (such as epilepsy) or reproductive disorders associated with PCOS Ask a doctor or a patient Not taking any of these items: tobacco; alcohol; anti-estrogens (such as tamoxifen and raloxifene); oral or injectable corticosteroids (such as prednisone, prednisolone, dexamethasone, triamcinolone, hydrocortisone or betamethasone); lack of omega-3 supplementation Chains and long chains); effective drugs for insulin resistance such as metformin and sitagliptin Non-consumption of any canola and olive oil in the last 6 months as the main consumer oil Lack of any allergy, intolerance or harmful drug reaction to the supplementation of the studied oils Being in the age range of 18-45 years (people are not better off at the age of growth and menopause) Being in the BMI range above 25 and less than 40 Ability to understand the goals of the study and provide informed written consent The desire to participate in the study Weight constant over the past 6 months (self report) Lack of Pregnancy and Breastfeeding

Exclusion criteria:

The onset of a dose or any change in dosage in the above drugs or the change in the type or dose of OCP consumed during the study period Getting pregnant during the study period Incidence of severe side effects or signs of poisoning with supplements used during the study period Failure to adhere to the study protocol The acceptance of less than 80% of the intervention (consumption of less than 80% of the total intervention oil that should be consumed during the 10-week intervention period will be considered as a low admission)

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were classified using randomized block splitting and divided into three groups using random numbers table.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients were randomly divided into three groups who were informed about entering the study and were not aware of the type of intervention received. On the other hand, the researcher who does all the information and measurements is also unaware of the type of intervention that each patient receives. A collaborator physician in the study was also blinded to this study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences. Hazar Jarib Street
City
isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-11-17, 1398/08/26
Ethics committee reference number
IR.MUI.RESEARCH.REC.1397.315

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
lipid profile
Timepoint
At the beginning of the study, 5 weeks after the intervention and the end of the study
Method of measurement
Spectrophotometric method

2

Description
Anthropometric Indicators
Timepoint
At the beginning of the study, 5 weeks after the intervention and the end of the study
Method of measurement
Measurements with biometric impedance analysis (BIA) and meters

3

Description
fatty liver grade
Timepoint
At the beginning of the study, 5 weeks after the intervention and the end of the study
Method of measurement
sonography

4

Description
mood disorder score
Timepoint
At the beginning of the study, 5 weeks after the intervention and the end of the study
Method of measurement
DASS-21 questionnaire

5

Description
Inflammatory Indicators
Timepoint
At the beginning of the study, 5 weeks after the intervention and the end of the study
Method of measurement
ELISA

Secondary outcomes

1

Description
Clinical signs including hirsutism and the interval between menstruation
Timepoint
At the beginning of the study, 5 weeks after the intervention and the end of the study
Method of measurement
MFGS questionnaire And the question of the patient

2

Description
blood pressure
Timepoint
At the beginning of the study, 5 weeks after the intervention and the end of the study
Method of measurement
Mercury barometric

Intervention groups

1

Description
Intervention group: 25 grams of olive oil
Category
Treatment - Other

2

Description
Intervention group: 25 grams of canola oil
Category
Treatment - Other

3

Description
Control group: 25 grams of sunflower oil
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Martyrs' clinic
Full name of responsible person
akbar samadi
Street address
Martyrs' clinic. Sepahanshahr. Nezam Street.
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Web page address

Sponsors / Funding sources

1

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Full name of responsible person
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Email
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Grant name
Thesis
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
60
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
Esfahan University of Medical Sciences
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Maryam Yahay
Position
Phd student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Proposals and consent form and published article from the study

When the data will become available and for how long

Getting Started October 1399

To whom data/document is available

Academic Institutions

Under which criteria data/document could be used

To give students access to their dissertations

From where data/document is obtainable

You can call 09134118836 for help

What processes are involved for a request to access data/document

After doing the research and publishing the paper, it will provide you with the documentation.

Comments