Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effect of psyllium oral supplementation on insulin resistance and lipid profile in non diabetic patients with polycystic ovary syndrome

Protocol summary

Summary

Objectives: The aim of current study to determine the effect of oral psyllium supplementation on insulin resistance and lipid profile in non-diabetic patients with polycystic ovary syndrome. Design: A randomized clinical trial, double-blind, placebo-controlled will be done on 54 females with polycystic ovary syndrome, non-diabetic. Setting and conduct: Patients will be divided randomly into 2 groups, intervention group (5 grams of psyllium) and placebo group (microcrystalline cellulose as a placebo) twice daily for 8 weeks. Participants: Inclusion criteria are including: patients who have FBS (fasting blood glucose) less than 126 mg /dl and age group 18 -45 years. Exclusion criteria: Subjects with diseases such as diabetes; congenital adrenal hyperplasia; Cushing's syndrome; thyroid disorders or corticosteroid consumers. Levels of fasting blood glucose, fasting insulin and lipid profile before and after intervention will be compared between two groups. Also, Diet and Anthropometric measurements of participants will be assessed in before and after the intervention duration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091929508N4**
Registration date: **2016-10-18, 1395/07/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-18, 1395/07/27

Registrant information

Name

Rasoul Zarrin

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2016-09-24, 1395/07/03

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of psyllium oral supplementation on insulin resistance and lipid profile in non diabetic patients with polycystic ovary syndrome

Public title

The effect of psyllium oral supplementation on insulin resistance and lipid profile in non diabetic patients with polycystic ovary syndrome

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Age range 18-45 years; PCOs diagnosis based on the Rotterdam; Persons with fasting glucose concentrations in the range of less than 126 mg /dl; Exclusion criteria: Smoker or addict; Individuals receiving glucose-lowering drugs other than Metformin;

Corticosteroid consumer; Consumer drugs such as Lithium, Carbamazepine and Digoxin; Warfarin consumer; Individuals with a history of Myocardial Infarction, Kidney, Liver and Lung diseases; Individuals with Thyroid Dysfunction; Individuals with major surgery in the last 6 months; Individuals with a history of allergy to Psyllium and Aspartame; Patients with Phenylketonuria; Patients with type 1 diabetes, Gastrectomy and Parkinson's disease; Individuals with a history of Gastrointestinal Disease, particularly persistent constipation and narrowing and blockage of the intestinal tract; Individuals treated with drugs that affect blood lipid profile; Individuals with a history of diseases such as Congenital Adrenal Hyperplasia, Cushing's syndrome, Hyperprolactinemia, the androgen-secreting tumors and Thyroid disease; Patients treated with antidepressant medications and recent treatment for eating disorder; Individuals treated with other fiber supplements.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, Urmia University of Medical Sciences

Street address
Urmia University of Medical Sciences, Jahad street, Resalt Ave, Urmia, Iran

City
Urmia

Postal code

Approval date
2016-08-31, 1395/06/10

Ethics committee reference number
Ir.umsu.rec.1395.223

Health conditions studied

1

Description of health condition studied
polycystic ovarian syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
fasting blood glucose (FBS)

Timepoint
before intervention, 2 month after intervention

Method of measurement
mg/dl

2

Description
fasting serum insulin

Timepoint
before intervention, 2 month after intervention

Method of measurement
µU/mL

3

Description
Triglyceride

Timepoint
before intervention, 2 month after intervention

Method of measurement
mg/dl

4

Description
Total Cholesterol

Timepoint
before intervention, 2 month after intervention

Method of measurement
mg/dl

5

Description
LDL-C

Timepoint
before intervention, 2 month after intervention

Method of measurement
mg/dl

6

Description
HDL-C

Timepoint

before intervention, 2 month after intervention

Method of measurement

mg/dl

7

Description

homeostasis model assessment of insulin resistance (HOMA-IR)

Timepoint

before intervention, 2 month after intervention

Method of measurement

FBS*insulin/22.5

Secondary outcomes

1

Description

Fat mass

Timepoint

before intervention, 2 month after intervention

Method of measurement

gr

2

Description

Body Mass Index (BMI)

Timepoint

before intervention, 2 month after intervention

Method of measurement

kg/m2

3

Description

Fat Free Mass

Timepoint

before intervention, 2 month after intervention

Method of measurement

gr

4

Description

Waist to hip ratio (WHR)

Timepoint

before intervention, 2 month after intervention

Method of measurement

waist/hip

5

Description

Number and regularity of menstrual cycle

Timepoint

before intervention, 2 month after intervention

Method of measurement

Ask a Question

Intervention groups

1

Description

Intervention group: 5 grams of Psyllium twice daily for 2 month

Category

N/A

2

Description

control group: 5 grams of Microcrystalline cellulose as a placebo, twice daily for 2 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam KHomeini Hospital

Full name of responsible person

Dr. Rasoul Zarrin

Street address

Emam KHomeini hospital, Ershad Street, Modarres Ave, Urmia, Iran

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Urmia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Urmia University of Medical Sciences, Jahad Street, Resalat Ave, Urmia

City

Urmia

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, Urmia 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
Urmia University of Medical Sciences
Full name of responsible person
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Assistant Professor of Nutrition
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