Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Inulin-type Fructans, with different degrees of polymerization, on metabolic parameters, hormonal status, inflammatory markers, oxidative stress, and endothelial dysfunction, in women with Polycystic Ovary Syndrome: A Randomized, Double-blind, Controlled, Clinical Trial

Protocol summary

Study aim

Evaluation of the Effect of Inulin-type Fructans, with different degrees of polymerization, on metabolic parameters, hormonal status, inflammatory markers, oxidative stress, and endothelial dysfunction, in women with Polycystic Ovary Syndrome

Design

A randomized, double blind, parallel, placebo-controlled clinical trial, on 75 women with Polycystic Ovary Syndrome. Randomization will be done by Permuted Block Randomization.

Settings and conduct

The present clinical trial will be conducted on 75 patients with Polycystic Ovary Syndrome. The diagnosis will be done by an expert gynecologist, based on Rotterdam criteria. The study duration will be 12 weeks. the Patients will be included in one of the three groups, including HPI, Oligofructose-enriched Inulin and placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria, including patients with Polycystic Ovary Syndrome, between 18 to 40 years old, BMI between 25 to 35, willingness to cooperate, not intended to become pregnant. Exclusion criteria, including pregnancy and lactation, smoking or alcohol use, being on specific diets or training plans, involved with other endocrine disorders or gastrointestinal disorders, current or previous (last 3 months) use of special drugs or supplements.

Intervention groups

Patients will be included in one of the following groups: 1)High Performance Inulin 2)Oligofructose-enriched Inulin 3)Maltodextrin as placebo

Main outcome variables

Anthropometric indices; dietary intakes; blood pressure; hirsutism severity score; quality of life score; mood disorders score; physical activity level; serum hs-CRP; serum Nitric Oxide; serum Endothelin-1; serum total Testosterone; serum lipid levels; fasting plasma glucose; fasting Insulin; serum SHBG; Free Androgen Index (FAI); Insulin resistance indices (QUICKI and HOMA-IR).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101101005062N11**
Registration date: **2020-11-10, 1399/08/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-10, 1399/08/20**
Update count: **0**

Registration date

2020-11-10, 1399/08/20

Registrant information

Name
Reza Ghiasvand

Name of organization / entity
Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01
Expected recruitment end date
2021-06-22, 1400/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Inulin-type Fructans, with different degrees of polymerization, on metabolic parameters, hormonal status, inflammatory markers, oxidative stress, and endothelial dysfunction, in women with Polycystic Ovary Syndrome: A Randomized, Double-blind, Controlled, Clinical Trial

Public title
The effect of Inulin-type Fructans, in treatment of Polycystic Ovary Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients between 18 to 40 years old BMI between 25 to 35 Kg/m2 Unwillingness to cooperate with the project Not intended to become pregnant
Exclusion criteria:
Current consumption (or during the previous 3 months) of oral contraceptive pills, hormone therapy, anti-diabetic or insulin sensitizing drugs, weight loss drugs, probiotic, synbiotic or prebiotic supplements, antibiotics, proton pomp inhibitors, multivitamin or mineral supplements or other nutritional supplements History of other endocrine disorders, including Thyroid disorders, Hyperprolactinemia, Cushing syndrome, Diabetes or Glucose Intolerance, and Androgenic disorders Pregnancy and lactation Smoking or alcohol consumption History of Gastrointestinal disorders, such as Inflammatory Bowel Diseases and Irritable Bowel Syndrome
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by Permuted Block Randomization, via the website, https://www.sealedenvelope.com/simple-randomiser/v1/lists. Each block has capacity for four subjects. After that, subjects will be randomly assigned to treatment or placebo groups, within each block. Random assignment will be done using a random chain, which will be extracted from the site.
Blinding (investigator's opinion)
Double blinded
Blinding description
Two ype of Inulin supplements and palcebo will be given to patients in similar packs. Both patients and the researcher are not aware of being in intervention or placebo group. Inulin supplements and placebo are relatively identical, in terms of color, taste and solubility.
Placebo
Used
Assignment
Parallel
Other design features
The patients will be divided into three groups: High Performance Inulin- Oligofructose-enriched Inulin- Placebo

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
School of Nutrition and Food Sciences, Isfahan University of Medical Sciences, Hezarjerib St, Isfahan, Iran
City
Isfahan
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Isfehan
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۷۳۴۶۱-۸۱۷۴۶
Approval date
2020-10-20, 1399/07/29
Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.471

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
The score of hirsutism severity in modified Ferriman-Galway Scale
Timepoint
At the beginning of the study, at the end of the sixth week and at the end of the study.
Method of measurement
modified Ferriman-Galway Scale

2

Description
Free Androgen Index
Timepoint
At the beginning of the study and at the end of the intervention.
Method of measurement
Based on serum total Testosterone and serum SHBG

3

Description
Serum hs-CRP
Timepoint
At the beginning of the study and at the end of the intervention.
Method of measurement
ELISA immunoassay kit

4

Description
Serum Endothelin-1
Timepoint
At the beginning of the study, and at the end of the study (end of the twelfth week).
Method of measurement
ELISA immunoassay kit

5

Description
Serum Fasting Plasma Glucose
Timepoint
At the beginning of the study, and at the end of the study (end of the twelfth week).
Method of measurement
Calorimetric assay

6

Description
Serum Fasting Insulin
Timepoint
At the beginning of the study, and at the end of the study (end of the twelfth week).
Method of measurement
ELISA immunoassay kit

7

Description
Insulin resistance
Timepoint
At the beginning of the study, and at the end of the study (end of the twelfth week).
Method of measurement
(Quantitative Insulin Sensitivity Check Index (QUICKI)

8

Description
Insulin resistance
Timepoint
At the beginning of the study, and at the end of the study (end of the twelfth week).
Method of measurement
Homeostatic Model Assessment Index (HOMA)

9

Description
Serum Triglyceride level
Timepoint
At the beginning of the study, and at the end of the study (end of the twelfth week).
Method of measurement
Calorimetric assay

10

Description
Serum Low-Density Lipoprotein (LDL-cholesterol)
Timepoint
At the beginning of the study, and at the end of the study (end of the twelfth week).
Method of measurement
Calorimetric assay

11

Description
Serum High-Density Lipoprotein (HDL-cholesterol)
Timepoint
At the beginning of the study, and at the end of the study (end of the twelfth week).
Method of measurement
Calorimetric assay

12

Description
Serum Total Cholesterol
Timepoint
At the beginning of the study, and at the end of the study (end of the twelfth week).
Method of measurement
Calorimetric assay

13

Description
Dietary intakes
Timepoint
At the beginning of the study, at the end of the sixth

week, and at the end of the intervention.

Method of measurement

Three-days Food Record

14

Description

Serum Nitric Oxide level

Timepoint

At the beginning of the study, and at the end of the study (end of the twelfth week).

Method of measurement

ELISA Immunoassay kit

15

Description

Serum Sex-Hormone Binding Globulin (SHBG)

Timepoint

At the beginning of the study, and at the end of the study (end of the twelfth week).

Method of measurement

ELISA Immunoassay kit

16

Description

Serum Total Testosterone

Timepoint

At the beginning of the study, and at the end of the study (end of the twelfth week).

Method of measurement

ELISA Immunoassay kit

17

Description

Mood status score

Timepoint

At the beginning of the study, and at the end of the study (end of the twelfth week).

Method of measurement

DASS-21 Questionnaire

18

Description

Quality of life score

Timepoint

At the beginning of the study, and at the end of the study (end of the twelfth week).

Method of measurement

PCOS quality-of-life questionnaire (PCOSQ)

Secondary outcomes

1

Description

Weight

Timepoint

At the beginning of the study, at the end of the sixth week and at the end of the intervention

Method of measurement

Standard weight scale

2

Description

Systolic and Diastolic blood pressure

Timepoint

At the beginning of the study, at the end of the sixth week and at the end of the intervention

Method of measurement

Digital Sphygmomanometer

3

Description

Body Mass Index

Timepoint

At the beginning of the study, at the end of the sixth week and at the end of the intervention

Method of measurement

It will calculated by weight divided by height (in meters)

Intervention groups

1

Description

Intervention group: High Performance Inulin group. With Degree of Polymerization equal or more than 22, with commercial name Frutafit® TEX, Sensus/Netherlands. The supplement will be given to patients in 10 grams packs. It should be consumed by dissolving in water or yogurt, with main meals.

Category

Treatment - Other

2

Description

Intervention group: Oligofructose-enriched inulin, with average Degree of Polymerization between 8 to 13, with commercial name Frutafit® IQ, Sensus/Netherlands. The supplement will be given to patients in 10 grams packs. It should be consumed by dissolving in water or yogurt, with main meals.

Category

Treatment - Other

3

Description

Control group: Maltodextrin powder, 10 grams per day. The placebo will be given to patients in 10 grams packs. It should be consumed by dissolving in water or yogurt, with main meals.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Zahra Shahshahan Private Gynecology office

Full name of responsible person
Rahele Ziaei and Zahra Shahshahan

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Molla-sadra building, Amadegah St, Isfahan, Iran

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Rahele Ziaei

Position
Ph.D student

Latest degree
Master

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not 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
Major parts of data will be available for the population.

When the data will become available and for how long
12 months after publishing the results.

To whom data/document is available
Available for academic researchers, who work in academic and scientific institutions.

Under which criteria data/document could be used
For conducting similar projects.

From where data/document is obtainable
Dr. Reza Ghiasvand ghiasvand@hlth.mui.ac.ir

What processes are involved for a request to access data/document
The data will be send one month after receiving the request.

Comments