

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 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 Ghasvand

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2742

Email address

ghiasvand@hlth.mui.ac.ir

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 pump 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/lits>. 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 type of Inulin supplements and placebo 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

Province

Isfahan

Postal code

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 be 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

Street address

Molla-sadra building, Amadegah St, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3221 1888

Email

r.ziaei92@gmail.com

2

Recruitment center

Name of recruitment center

Saint Al-zahra Hospital Gynecology and ObstetricsClinic

Full name of responsible person

Rahele Ziaei and Dr. Zahra Shahshahan

Street address

Gynecology and Obstetrics Clinic, Al-zahra Hospital, Soffe St, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3668 5555

Email

alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

Street address

Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 5149

Email

research@mui.ac.ir

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

Street address

School of Nutrition and Food Sciences, Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8487

Email

r.ziaei92@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Reza Ghiasvand

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

School of Nutrition and Food Sciences, Isfahan

University of Medical Sciences, Isfahan, Iran

r.ziaei92@gmail.com

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8487

Email

ghiasvand@hlth.mui.ac.ir

Person responsible for updating data

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

Street address

Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8487

Email

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