

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Effect of Sumac powder on Antioxidant indices and Uric Acid in women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to investigate the effect of Sumac powder on antioxidant indices and Uric acid in women with polycystic ovary syndrome who referring to Akbar Abadi Hospital.

Design

The clinical trial has a control group, double-blind, and randomized. For randomization, a random block method with four block was used. The number of samples in each group was 37, which is assumed to be 15 percent reduction, 44 people were considered in each group.

Settings and conduct

This study is a randomized, double-blind clinical trial (patient and researcher). The place of study is Akbar Abadi Hospital. The number of 88 patients with polycystic ovary syndrome after the examination by a Gynecologist, filling out the demographic questionnaire, 24-hour recall, physical activity is divided into two groups in each group 1- intervention group receives sumac powder 2- control group receives starch randomly (3 capsules each capsule containing 1gr). The placebo prepares with the same appearance and randomly divides it into patients. To compare the two groups at the beginning and after the study, Antioxidant indices and Uric acid will evaluate.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the patient's with polycystic ovary syndrome; Age between 20 and 40; Written consent of the patient. Non-inclusion criteria: reluctance to participate in the plan; ; conditions that affect insulin sensitivity, inflammation or lipid profile and hormonal profile.

Intervention groups

Intervention group: Patients who have inclusion criteria and receive one capsule contains 3 gr sumac powder.
Control group: Patients who have inclusion criteria receive 3 gr Starch for three months.

Main outcome variables

Malondialdehyde; glutathione peroxidase; superoxide

dismutase; total antioxidant capacity and uric acid

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009472N21**

Registration date: **2020-01-06, 1398/10/16**

Registration timing: **retrospective**

Last update: **2020-01-06, 1398/10/16**

Update count: **0**

Registration date

2020-01-06, 1398/10/16

Registrant information

Name

Naheed Aryaeian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4750

Email address

aryaeian.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2019-11-19, 1398/08/28

Actual recruitment start date

2018-04-04, 1397/01/15

Actual recruitment end date

2019-11-19, 1398/08/28

Trial completion date

2019-11-19, 1398/08/28

Scientific title

Effect of Sumac powder on Antioxidant indices and Uric Acid in women with polycystic ovary syndrome

Public title

Effect of Sumac in treatment of polycystic ovary syndrome

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Polycystic ovary Syndrome based on two criteria of the three diagnostic criteria of the disease based on Rotterdam: 1. Bleeding is reduced or discontinued (as Delay more than 35 days or less than 8 bleeding episodes per year) 2. Clinical symptoms including hirsutism or Ferriman-Gallway (MGF) score above 8, acne and male pattern baldness and biochemical symptoms of increased androgenesis. 3. Polycystic ovary (12 or more of 12 follicles per ovary with a diameter of 2 to 9 mm, or an increase in ovarian volume to more than 310 ml). Patients with age between 20 to 40 years old. patient's acceptance of taking part in the study.

Exclusion criteria:

Those who take drugs of anticoagulants and hyperlipidemia Use Tobacco Having kidney disease, diabetes, liver disease, cardiovascular disorders, hypothyroidism, inflammatory and rheumatic diseases, hyperprolactinemia, Cushing's syndrome, and congenital adrenal hyperplasia Follow a particular diet in the last three months. Take medications that affect insulin sensitivity, inflammation, or lipid profile and hormonal profile, including glucocorticoid drugs, ovulation induction drugs, anti-obesity, anti-diabetes, antihypertensive, estrogenic, anti-androgen, over the past 3 months Unwilling to participate in the study Use of Nutrition Supplements in the last 2 months Pregnancy or breastfeeding Sensitization or allergy to sumac

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **88**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the method of block randomization will be used with quadrilateral blocks. According the sample size of 88, the 22 quadruple blocks will be

produced. For the purpose of concealment in the randomization process, individual codes will be used on supplements boxes that code is also generated by the software. By intering each persons to study, Based on the generated sequence, Supplementary box that code has been registered on that, will allocate to the person.

Blinding (investigator's opinion)

Double blinded

Blinding description

For the purpose of concealment in the randomization process, individual codes will be used on supplements boxes that code is also generated by the software. This study is a two-blind study in which participants, principal investigator and health care personnel are keeping blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Science

Street address

Iran University of Medical Science, Next to Milad tower, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2019-12-10, 1398/09/19

Ethics committee reference number

IR.IUMS.REC.1398.193

Health conditions studied**1****Description of health condition studied**

Polycystic ovary syndrome

ICD-10 code

Poly cysti

ICD-10 code description

E28.2

Primary outcomes**1****Description**

serum malondialdehyde

Timepoint

Before intervention and 3 months after intervention

Method of measurement

colorimetric method

2

Description

glutathione peroxidase

Timepoint

Before intervention and 3 months after intervention

Method of measurement

colorimetric method

3

Description

superoxide dismutase

Timepoint

Before intervention and 3 months after intervention

Method of measurement

colorimetric method

4

Description

total antioxidant capacity

Timepoint

Before intervention and 3 months after intervention

Method of measurement

elisa method

5

Description

uric acid

Timepoint

Before intervention and 3 months after intervention

Method of measurement

turbiditymetry method

Secondary outcomes

1

Description

Dietry intake

Timepoint

Before intervention and 3 months after intervention

Method of measurement

24-hour questionnaire food intake for 3 days and analysis with N4 software

2

Description

Anthropometric indices

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Meters, scales and computing

3

Description

Physical activity

Timepoint

Before intervention and 3 months after intervention

Method of measurement

International Physical Activity Questionnaire

Intervention groups

1

Description

Control group: Patients referring to Akbar Abadi Hospital who are willing to cooperate and have inclusion criteria will receive starch. They will use 3 gram Starch from Golha factory (3 capsules of 1 gram) for 3 months.

Category

Placebo

2

Description

Intervention group: Patients referring to Akbar Abadi Hospital who are willing to cooperate, have inclusion criteria. and receive sumac powder. They will consume 3 gram sumac making by the Golha factory (3 capsules of 1 gram) for 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbar Abadi Hospital

Full name of responsible person

Dr maryam Kashanian

Street address

Shahid Akbar Abadi Hospital, Baghe Ferdows station, Molavi street

City

Tehran

Province

Tehran

Postal code

1168743514

Phone

+98 21 5560 6034

Fax

Email

maryamkashanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevallian

Street address

Iran University of Medical Science, Next to Milad tower, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

n-aryaeian@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Research deputy of Iran University of Medical Science

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

n-aryaeian@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Naheed Aryaeian

Position

Faculty member(Associate professor)

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Nutrition group, School of health, Iran University Of Medical Science, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 4750

Fax

+98 21 8862 2707

Email

n-aryaeian@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Naheed Aryaeian

Position

Faculty member(Associate professor)

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

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Tehran

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۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 4750

Fax

+98 21 8862 2707

Email

aryaeian.n@iums.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Position

Faculty member(Associate professor)

Latest degree

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Fax

+98 21 8862 2707

Email

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the questionnaires includes demographic information, 24-hour recall, physical activity, as well as clinical and biochemical outcomes

after unidentifiable individuals will be publish.

When the data will become available and for how long

The start of access period is from 1399 solar year equivalent to 2020 A.D

To whom data/document is available

All individuals, including researchers who working in university and scientific places, physicians, nutritionists and those engaged in the industry, can use these documentations.

Under which criteria data/document could be used

Use of the documentation is permitted if there is no copyng and no citation or inappropriate citation.

From where data/document is obtainable

Dr Nahid Aryaeian

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

If the journal is free, the documents is availabe at the scientific search bases. Otherwise will need to pay money.

Comments