Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

Effect of sumac on Clinical Signs, Hyperandrogenism, Reactive Protein C and profile of lipidis and glycemic status in women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to investigate the effect of sumac powder on clinical signs, hyperandrogenism, C-reactive protein , Blood glucose and Lipid profile in women with polycystic ovary syndrome (PCOS) who referring to Shahid Akbar Abadi Hospital.

Design

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

Settings and conduct

This study is a randomized, double blind randomized clinical trial (both patient and researcher). The place of study is Shahid Akbar Abadi Hospital. The number of 88 patients with polycystic ovary syndrome in the range of 20 to 40 years after the examination by an Gynecologist filled out the demographic questionnaire, 24-hour recall, physical activity were divided into two groups with 44 patients in each group,1- intervention group receiving one capsule containing sumac powder 2-control group randomly. Patients in The intervention group will receive 3 capsules each capsule containing 1 g of sumac powder daily and the control group will receive 3 capsule each capsule containing one grams starch, for 3 months. The placebo will prepare with the same appearance and randomly will divide into patients. To compare the two groups at the beginning and after the study, the Fasting blood glucose, Serum Insulin, lipid profile, testosterone, DHEA, 17-hydroxyprogesterone, androstenedione, LH, FSH, protein C-reactive, clinical signs and anthropometric indicators will evaluate.

Participants/Inclusion and exclusion criteria

The inclusion criteria are: the patient's with polycystic ovary syndrome based on Rotterdam criteria; Age is between 20 and 40; Written consent of the patient. Non-inclusion criteria are: reluctance to participate in the plan; Follow a particular diet in the past 3 months or use supplements in the last 2 months; Sensitivity and allergies; Pregnancy and lactation; Smoking;Taking medications that affect insulin sensitivity, inflammation or lipid profile and hormonal profile; kidney diseased; diabetes; hepatic diseases; cardiovascular disorders; hypothyroidism; inflammatory and rheumatic diseases; hyperprolactinemia; Cushing's syndrome and congenital adrenal hyperplasia.

Intervention groups

Control group: Patients referring to Akbar Abadi Hospital who are willing to cooperate and have inclusion criteria will receive 3 gr Starch (3 capsules of 1 gram) for 3 months Intervention group: Patients referring to Akbar Abadi Hospital who are willing to cooperate and have inclusion criteria will receive 3 gr sumac (3 capsules of 1 gram) for 3 months

Main outcome variables

Insulin resistance; Fasting blood sugar; fasting insulin; lipid profiles (LDL, HDL, TG, total cholesterol); total testosterone; DHEA (dehydroupiandrosterone); 17-hydroxyprogesterone; androstenedione; luteinizing hormone (LH); follicular stimulatory hormone (FSH); C-reactive protein (Hs-CRP); hirsutism scars; acne; baldness and loss of hair

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009472N17**
Registration date: **2018-02-19, 1396/11/30**
Registration timing: **prospective**

Last update: **2018-02-19, 1396/11/30**
Update count: **0**

Registration date
2018-02-19, 1396/11/30

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-04, 1397/01/15
Expected recruitment end date
2019-03-20, 1397/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of sumac on Clinical Signs, Hyperandrogenism, Reactive Protein C and profile of lipidis and glycemic status in women with polycystic ovary syndrome

Public title
Effect of sumac on Clinical, Hormonal and inflammatory signs and blood sugar and lipids amount in women with 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 Rotterdam1. Reduction of bleeding or discontinuation (as: Delay more than 35 days or less than 8 bleeding episodes per year); 2. Clinical symptoms including hirsutism or Ferriman-Gallwey (MFG) score above 8,acne and Male pattern baldness, biochemical symptoms of increased endogenesis ,3.polycystic ovary (12 or more of 12 follicles per ovary with diameter of 2 to 9 mm , or an increase in ovarian volume to more than 310 ml) Reduction of bleeding or discontinuation (as: Delay more than 35 days or less than 8 bleeding episodes per year); Clinical symptoms including hirsutism or Ferriman-Gallwey (MFG) score above 8,acne and Male pattern baldness biochemical symptoms of increased endogenesis polycystic ovary (12 or more of 12 follicles per ovary with diameter of 2 to 9 mm , or an increase in ovarian volume to more than 310 ml) Age 20 to 40 years old Having informed written consent
Exclusion criteria:
Taking drug of anticoagulants and hyperlipidemia Use of 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 Taking 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
- Data analyser

Sample size
Target sample size: **88**
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 entering each person 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)
Triple 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 three-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 Sciences
Street address
Sheikh Fazlolah Noori, Hemmat Highway, Iran University of Medical Sciences
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Approval date
2018-02-06, 1396/11/17
Ethics committee reference number
IR.IUMS.REC 1396.31930

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description
Poly cystic ovarian syndrome

Primary outcomes

1

Description
Insulin resistance
Timepoint
before intervention and 3 months after intervention
Method of measurement
HOMA-IR method

2

Description
Fasting Blood Sugar
Timepoint
before intervention and 3 months after intervention
Method of measurement
colorimetric assay method

3

Description
Fasting insulin
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Chemiluminescence assay

4

Description
Lipid Profile (LDL, HDL, TG, Total Cholesterol)
Timepoint
before intervention AND 3 months after intervention
Method of measurement
colorimetric assay method

5

Description
Total Testosterone
Timepoint
before intervention AND 3 months after intervention
Method of measurement
ELIZA method

6

Description
DHEA (Dehydroepiandrosterone)
Timepoint
before intervention and 3 months after intervention
Method of measurement
ELIZA method

7

Description
17-hydroxy Progesterone
Timepoint
before intervention and 3 months after intervention
Method of measurement
ELIZA method

8

Description
Androstenedione
Timepoint
before intervention and 3 months after intervention
Method of measurement
ELIZA method

9

Description
Luteinizing Hormone (LH)
Timepoint
before intervention AND 3 months after intervention
Method of measurement
ELIZA method

10

Description
Follicle stimulating hormone(FSH)
Timepoint
before intervention and 3 months after intervention
Method of measurement
ELIZA method

11

Description
C-reactive protein (hs-CRP)

Timepoint
before intervention and 3 months after intervention
Method of measurement
Turbidimetry method

12

Description
hirsutism score
Timepoint
Before intervention AND 3 months after intervention
Method of measurement
Calculation based on Freeman-Gallo method

13

Description
Acne
Timepoint
before intervention AND 3 months after intervention
Method of measurement
Face check

14

Description
Baldness and hair loss
Timepoint
before intervention AND 3 months after intervention
Method of measurement
Hair Head check

Secondary outcomes

1

Description
Dietary intake
Timepoint
Before intervention and three months after intervention
Method of measurement
Nutrition 24-hour questionnaire feed and analysis with N4 software

2

Description
Anthropometric indicators
Timepoint
Before intervention and three months after intervention
Method of measurement
Meters, scales and Computing

3

Description
Physical activity
Timepoint
Before intervention and three months after intervention
Method of measurement
International Physical Activity Questionnaire

4

Description
Body fat percentage
Timepoint
Before intervention and three months after intervention
Method of measurement
BIA method with ebody device

5

Description
Menstrual cycle order
Timepoint
Before intervention and three months after intervention
Method of measurement
Question from the patient

Intervention groups

1

Description
Control group: Patients referring to Akbar Abadi Hospital who are willing to cooperate and have inclusion criteria will receive 3 gr Starch(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 and have inclusion criteria will receive 3 gr sumac (3 capsules of 1 gram) for 3 months
Category
Other

Recruitment centers

1

Recruitment center
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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
Iran 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

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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
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 the access period is from 1398 solar year equivalent to 2019 A.D.

To whom data/document is available
All individuals, including researcher who working in university and scientific places,physician, 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 copying and no citation or inappropriate citation.

From where data/document is obtainable
Dr Naheed Aryaeian

What processes are involved for a request to access data/document
If the journal is free, the documents is available at the scientific search bases۹ Otherwise, will need to pay money.

Comments