Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of salvia officinalis extract capsules on health indexes of women with policyctic ovary syndrome

Protocol summary

Summary

The main objective of the study: the effect of oral Salvia officinalis extracts capsules on metabolic parameters, oxidative stress and general health in women with polycystic ovary syndrome / study method: randomized clinical trial, placebo-controlled, triple-blind. / Samples: all Iranian women with polycystic ovary syndrome who were referred to infertility and gynecology clinics of the Firouzgar hospital and approved private centers having at least two of three Rotterdam consensus criteria will participate. Women should not have taken any food supplements, hormonal drugs (except oral contraceptive compounds), reducing or increasing the weight compounds, The blood lipid lowering drugs, The blood glucose lowering drugs and Anti-epileptic drugs should not have been used during the study and two months before it and patients with chronic physical diseases and mentally disorders, addicted to drugs and having allergy to salvia officinalis, will be excluded. After approval of ethical committee of Iran University of Medical Sciences all patients will give their written informed consents and then the samples with triple-blind manner will be randomly divided into two groups: treatment with oral salvia officinalis extract or placebo. Before any intervention all participants will fill the Demographic information questionnaire, Health history form and GHQ28 (general health questionnaire) and after 12 to 14 hours of fasting 10 cc of blood will be collected to measure glucose, insulin, cholesterol, high density lipoprotein cholesterol (HDL), low density lipoprotein cholesterol (LDL) , triglycerides and markers of oxidative stress (MDA, TAC) from each participant. The experimental group who will receive salvia officinalis alcoholic extract 150 mg capsules twice a day orally and the control group will take similar capsules with Starch as a placebo for 8 weeks. After 2 months of study blood will be taken from all subjects for assessment metabolic and oxidative stress markers and GHQ-28 questionnaire will be filled again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504146917N2**
Registration date: **2015-10-03, 1394/07/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-03, 1394/07/11

Registrant information

Name
Leila Amini
Name of organization / entity
Tehran University of Medical Science
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of salvia officinalis extract capsules on health indexes of women with policyctic ovary syndrome

Public title
Effect of sage on health of women with polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1-The samples should have the desire to participate in the study and informed consent was taken from them. 2- They should have Iranian nationality. 3- Don’t use food and drug supplements such as vitamins, minerals... 4- They shouldn't be on a special diet such as Low-sugar, low-fat or vegetarian diets. 5- Absence of known mental illness or chronic physical disease according to the information given from the patient. 6- They shouldn't be pregnant and has no desire to become pregnant during the study. 7- The participant and her wife, shouldn't be addicted to drugs and also shouldn't take any tranquilizers or psychotropic substances. 8 -Hormonal drugs (except oral contraceptive compounds), reducing or increasing the weight compounds, the blood lipid lowering drugs, the blood glucose lowering drugs and Anti-epileptic drugs should not have been used during the study and two months before it. 9- They are not undergoing infertility treatment. 10- They should not have been under the influence of stressful events during the last three months. Exclusion criteria: 1- Participants withdrew from participating in the study at any part of study. 2- In case of intolerable or harmful side effects, such as severe nausea and vomiting or allergy caused by the salvia officinalis capsules.

Age
From **15 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway

City
Tehran

Postal code
1449614535

Approval date
2015-08-05, 1394/05/14

Ethics committee reference number
IR.IUMS.REC.1394.9211373221

Health conditions studied

1

Description of health condition studied
Policyctic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description
Wheight

Timepoint
Before intervention and 8 weeks after intervention

Method of measurement
Weight in kilograms

2

Description
Waist circumference

Timepoint
Before intervention and 8 weeks after intervention

Method of measurement
Centimetre

3

Description
Hip circumference

Timepoint
Before intervention and 8 weeks after intervention

Method of measurement
Centimetre

4

Description

Body Mass Index (BMI)

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Is defined as the body mass divided by the square of the body height, and is universally expressed in units of kg/m2

5

Description

Systolic and diastolic blood pressure

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Will be measured with Sphygmomanomete in millimeters of mercury (mm Hg)

6

Description

Fasting Blood Sugar (FBS)

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Venous blood samples will be collected and then enzymatic colorimetricd methode using special kits and autoanalyzer will be measured in milligrams per deciliter

7

Description

Triglyceride

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Venous blood samples will be collected and then enzymatic colorimetricd methode using special kits and autoanalyzer will be measured in milligrams per deciliter

8

Description

Cholestrol

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Venous blood samples will be collected and then enzymatic colorimetricd methode using special kits and autoanalyzer will be measured in milligrams per deciliter

9

Description

Low density lipoprotein cholesterol (LDL)

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Venous blood samples will be collected and then enzymatic colorimetricd methode using special kits and autoanalyzer will be measured in milligrams per deciliter

10

Description

High density lipoprotein cholesterol (HDL)

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Venous blood samples will be collected and then enzymatic colorimetricd methode using special kits and autoanalyzer will be measured in milligrams per deciliter

11

Description

Malondialdehyde (MDA)

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

The MDA-TBA adduct formed by the reaction of MDA and TBA under high temperature. Malondialdehyde is measured in colorimetrically at 532 in nmol/lit

12

Description

Total antioxidant capacity

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

According to ability for reducing Fe+3 to Fe+2, which can combine with phenanthrene and form a colored compound. According to the chemical colorimetry / mmol/lit

13

Description

Fasting insulin level

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Human Insulin ELISA Kit in picomol/lit (or µU/mL)

14

Description

General mental health

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

General health questionnaire - 28 (GHQ-28)

Secondary outcomes

empty

Intervention groups

1

Description

The experimental group will receive salvia officinalis alcoholic extract 150 mg capsules twice a day orally for 8

weeks .

Category

Treatment - Drugs

2

Description

The control group will take similar capsules with starch as a placebo twice a day for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital, infertility clinic

Full name of responsible person

Dr. Zahra Raoufi

Street address

Firoozgar hospital, Behafarin St., Valiasr Sq.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research & Technology

Street address

5th floor - central committee - Iran University of Medical Sciences - Shahid Hemmat Highway

City

Tehran

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

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

Iran University of Medical Sciences, School of Nrsing and Midwifery

Full name of responsible person

Arezoo Malaki hajiagha

Position

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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