Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The effect of cinnamon powder on anthropometric, metabolic and hormonal factors in patients with polycystic ovarian syndrome

Protocol summary

Summary

General Purpose :The effect of cinnamon powder on the anthropometric, metabolic and hormonal factors in patients with polycystic ovarian syndrome Double blind clinical trial, Phase 2, Parallel Total sample count: 60 person, divided in two equal groups، Study time: 12 weeks. Randomization method : simple blocks patients in the case group would take capsules containing 500 mg of cinnamon powder, 3 times a day (morning, afternoon, evening) after meal, along with an standard classic treatment (10 mg medroxyprogesterone tablets daily, from the 15th day of menstruation for 10 days) Patients in the control group: would take 500 mg capsules containing starch with slight amount of cinnamon as placebo, 3 times a day (morning, afternoon, evening), after a meal, along with an standard classic treatment (10 mg medroxyprogesterone tablets daily, from the 15th day of menstruation for 10 days) Inclusion criteria: Informed consent for study participation، diagnosis of polycystic ovary syndrome according to Rotterdam criteria، Age of 18 to 45 years، Body mass index (BMI): equal or greater than 18. Exclusion criteria: Any diseases that would affect study parameters (such as diabetes, liver disease and etc,.) based on the patient's previous history، Taking blood pressure medications, statins, insulin injections and other anti diabetic drugs، Pregnancy، Breast-feeding ، Allergy to cinnamon. out comes: A change in anthropometric profile of patients including weight, body mass index, waist and hip circumference at the beginning and the end of the study. Changes in biochemical parameters of patients bodies including fasting blood glucose, two hour blood glucose, serum insulin levels and lipid profile at the beginning and the end of the study. Change in serum androgen levels at the beginning and the end of the study.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015121525537N1**
Registration date: **2016-04-08, 1395/01/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-08, 1395/01/20

Registrant information

Name
Mahdie Hajimonfared
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 3648 1433
Email address
hajimonfar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cinnamon powder on anthropometric, metabolic and hormonal factors in patients with polycystic ovarian syndrome

Public title
The effect of cinnamon on polycystic ovarian syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: informed consent to participate in the study؛ polycystic ovary syndrome diagnostic criteria Rotterdam are two of three of the following symptoms: i abnormal menstrual cycles (oligo dysmenorrhea, amenorrhea) ii polycystic ovaries on ultrasound iii clinical signs of hyperandrogenism (hirsutism -acne-) or biochemical signs of hyperandrogenism and also reject and Cushing's syndrome and congenital adrenal hyperplasia؛ age 45-18 years ؛Body mass index (BMI) greater than or equal to 18. Exclusion criteria: any disease affecting variables (diabetes, liver disease, thyroid, cardiovascular, renal, gastrointestinal, Cushing's syndrome, adrenal hyperplasia, androgen-secreting tumors, hyperprolactinemia) based on the patient's previous history؛ Taking blood pressure medications or statins or anti-diabetic drugs and insulin injections ؛Pregnancy ؛Breast-feeding ؛use of any vitamin supplements, minerals and hormones for at least two months before the study ؛being under the special diet ؛Consumers oral contraceptives (OCP), glucocorticoids, anti-androgens, ovulation induction drugs ؛consumers of tobacco and alcohol ؛a history of allergy to cinnamon
Age
From **18 years** old to **45 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)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
medical faculty, Zand Boulevard, Shiraz
City
Shiraz
Postal code
Approval date
2015-12-15, 1394/09/24
Ethics committee reference number
IR.sums.REC.1394.160

Health conditions studied

1

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

Primary outcomes

1

Description
weight, body mass index, waist and hip
Timepoint
Before study and after 12 weeks
Method of measurement
questionnaire

2

Description
fasting blood glucose, two hour blood glucose, serum insulin levels, lipid profile
Timepoint
Before study and after 12 weeks
Method of measurement
Blood sample

3

Description
serum androgen levels
Timepoint
Before study and after 12 weeks
Method of measurement
Blood sample

Secondary outcomes

1

Description

The menstrual cycle regularity

Timepoint

Before study and after 12 weeks

Method of measurement

Questions from Patients

Intervention groups

1

Description

Capsules containing 500 mg of cinnamon powder, 3 times a day (morning, afternoon, evening), after a meal with a standard treatment regimen (10 mg medroxyprogesterone tablets،from the 15th day of menstruation for 10 days

Category

Treatment - Drugs

2

Description

Control group: contains starch as placebo capsules, 3 times a day (morning, afternoon, evening), after a meal with a standard treatment regimen (10 mg medroxyprogesterone tablets،from day 15 of the menstrual period 10 days).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

Mahdie Hajimonfared

Street address

Motahari Clinic, Namazi Square, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Shiraz University of Medical Sciences

Full name of responsible person

Mahdie Hajimonfared

Street address

medical faculty ، Zand Boulevard, Shiraz

City

Shiraz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research,Shiraz 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

Shiraz University of medical science

Full name of responsible person

Mahdie Hajimonfared

Position

MD

Other areas of specialty/work

Street address

Shiraz, Zand Boulevard, medical faculty

City

Shiraz

Postal code

Phone

+98 71336481433

Fax

Email

hajimonfared@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

shiraz university of medical sciences

Full name of responsible person

Behie Namavar Jahromi

Position

Professor of female infertility

Other areas of specialty/work

Street address

Shiraz, Zand Boulevard, Shahid Faghihi hospital, section of women

City

shiraz

Postal code

Phone

+98 71332332365

Fax

Email

namavar@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mahdie Hajimonfared

Position

Other areas of specialty/work

Street address

City

Postal code

Phone
+98 71 3648 1433

Fax

Email

Web page address

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