Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Garlic (Allium sativum) consumption on indices of oxidative stress, insulin resistance, lipid profile and testosterone hormone in women with polycystic ovary syndrome(PCOS)

Protocol summary

Study aim
The effect of garlic intake on oxidative stress, insulin resistance, lipid profile and testosterone hormone in women with PCOS

Design
This study is a double blind randomized clinical trial. The block randomization method is used. The randomization unit is individual. The randomization tool is a random number table. The sample size is 68 people.

Settings and conduct
We select 68 women with PCOS referring to a gynecologist's office using available sampling.Then we randomly divide them into 2 groups of garlic and placebo tablets.Then their fasting blood samples are taken and we will give 800 mg of garlic or placebo tablet to each intervention group for daily intervention. After 8 weeks fasting blood samples will be taken to determine relevant markers.In this study, all participants, executor of plan, researcher, health care personnel such as physician and all laboratory personnel are kept blind to assigned study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria:minimum age 18 and maximum 45 years Not following a specific diet or exercise program Not taking any of: Alcohol, tobacco, anti-estrogens, oral or injectable corticosteroids, anticoagulants like warfarin and heparin and not taking aspirin No history of any allergy or intolerance to garlic and its products Do not take garlic pills or supplements containing garlic at least 2 months before intervention Not being pregnant, Lactation or menopause No other endocrine disorders Not using any drug or surgical treatment to treat clinical symptoms and disorders (PCOS) except OCP and metformin

Intervention groups
We will give 800 mg of garlic or placebo daily to each intervention group to start the intervention.

Main outcome variables
Effect of Garlic Tablets on Insulin Resistance of Glucose Levels, Antioxidant Capacity (TAC), Malondialdehyde (MDA), Lipid Profile and Testosterone Hormone in Patients with PCOS

General information

Reason for update
The reason for updating is to add new variables and code of ethics related to the new variables to the current research. Due to adding new variables to the current study, this research has two codes of ethics.

Acronym

IRCT registration information
IRCT registration number: **IRCT20161203031212N2**
Registration date: **2020-02-26, 1398/12/07**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-13, 1399/12/23**
Update count: **1**

Registration date
2020-02-26, 1398/12/07

Registrant information

Name
Forugh Fasihi
Name of organization / entity
Isfahan University of Medical Sciences, School of Nutrition and Food Sciences, Dept
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-20, 1398/12/01
Expected recruitment end date
2020-04-20, 1399/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Garlic (Allium sativum) consumption on indices of oxidative stress, insulin resistance, lipid profile and testosterone hormone in women with polycystic ovary syndrome(PCOS)

Public title
The effect of garlic on polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All women with polycystic ovary syndrome who are at least 18 and up to 45 years old
Exclusion criteria:
People who follow a certain diet People who follow a specific exercise program People undergoing any drug treatment such as spironolactone, finasteride, isotretinoin, letrozole, clomiphene, gonadotropins, rosiglitazone, pioglitazone, or surgery such as laparoscopic ovarian surgery and assisted reproductive technology (PCOS) to treat symptoms they do Any serious or significant systemic illness requiring treatment such as cancer, gastrointestinal, hepatic or endocrine disorders, thyroid dysfunction, diabetes mellitus, hyperprolactinemia, cardiovascular disorders, renal disorders, blood coagulation disorders, neurological disorders, Insomnia, Pemphigus Disease, Joint Rheumatism and Non-Related Reproductive Disorders (PCOS) History of pregnancy hypertension Family history of stroke Any of the following: Alcohol, tobacco, anti-estrogens, oral or injectable corticosteroids Pregnancy lactation Menopause Use of anticoagulants such as warfarin and heparin, Taking aspirin History of any allergy, intolerance or harmful drug reaction to garlic and its products Taking garlic pills or supplements containing garlic at least 2 months before the intervention
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization is used. The randomization unit is individual. The randomization tool is a random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blind clinical trial. In this study, all participants, executor of plan, researcher, health care personnel such as physician and all laboratory personnel are kept blind to assigned study groups.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezarjarib Street, Isfahan
City
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Province
Isfehan
Postal code
8174673461
Approval date
2019-06-26, 1398/04/05
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.187

2

Ethics committee
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Approval date

2021-03-10, 1399/12/20

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.806

Health conditions studied

1

Description of health condition studied

Polycystic Ovarian Syndrome(PCOS)

ICD-10 code

E28.2

ICD-10 code description

Polycystic Ovarian Syndrome(PCOS)

Primary outcomes

1

Description

Total Antioxidant Capacity (TAC)

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Colorimetric method

2

Description

Malon Di Aldehyde (MDA)

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Colorimetric method

3

Description

Lipid profile

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Spectrophotometry

4

Description

Fasting blood sugar(FBS)

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Spectrophotometry

5

Description

Insulin

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

It will be measured by ELISA kit

6

Description

Insulin Resistance (HOMA-IR)

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Will be measured computationally

7

Description

Testosterone hormone

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

It will be measured by ELISA kit

8

Description

glutathione(GSH)

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Colorimetric method

9

Description

Catalase(CAT)

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Colorimetric method

10

Description

Sex Hormone Binding Globulin (SHBG)

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

It will be measured by ELISA kit

Secondary outcomes

1

Description

blood pressure

Timepoint

Before the intervention and 2 months after the

intervention

Method of measurement

sphygmomanometer

2

Description

Weight

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Balance

3

Description

Body Mass Index(BMI)

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Balance and meter

4

Description

Waist

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

meter

5

Description

Around the abdomen

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

meter

6

Description

Hip circumference

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

meter

Intervention groups

1

Description

Intervention group: The intervention group consumed 800 mg of garlic tablets daily for 2 months.

Category

Treatment - Other

2

Description

The control group consumed 800 mg of placebo daily for 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

Amir Mansuor Alavi

Street address

Amin Hospital, Shohada Square, Ibn Sina Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

Amir Mansour Alavi Naini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Contact

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Full name of responsible person

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Roya Zadhoush

Position

Msc Student Nutrition Science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

If the individual data of the sample is unrecognizable, sharing the whole data is fine.

When the data will become available and for how long

3 months after the results

To whom data/document is available

This data is only available to academic researchers.

Under which criteria data/document could be used

The data is for personal use only and is not licensed for analysis.

From where data/document is obtainable

Amir Mansour Alavi Naini Email address: am.alavi@nutr.mui.ac.ir

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

The applicant can send his application to the responsible author's email address and after reviewing the application, documentation is provided to the applicant.

Comments