Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

To evaluate the effect of garlic tablet on metabolic syndrome in PCOS patients : A Randomized Double-blind Placebo-controlled Trial

Protocol summary

Study aim

The effect of garlic tablets on metabolic syndrome in patients with poly cystic ovary syndrome(PCOS)

Design

A randomized, double-blind, placebo-controlled clinical trial with control group in parallel with a calculated sample size of 36 patients in each group totaling 72 patients.

Settings and conduct

Samples were selected from women referring to the infertility clinic of Arash Women General Hospital who met the inclusion criteria and were randomly assigned to one of two intervention or control groups. The intervention duration is 8 weeks and these patients will be evaluated at the beginning of the study and at the end of the eighth week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 15 to 49 years / unwilling to participate in the study / not pregnant / not having diabetes Mellitus / not having other chronic illnesses / not taking blood lipids and anticoagulants / minimal reading and writing literacy / Consume a maximum of one garlic per day Exclusion criteria: unwillingness to continue participation / occurrence of any side effects caused by medication and intervention.

Intervention groups

Intervention group: Garlic tablets 500 mg twice daily for 8 weeks along with other medications such as Metformin Control group: Garlic placebo in the same dose and form for 8 weeks.

Main outcome variables

Plasma Level of FBS/ Triglyceride/ HDL/Cholesterol total Level of systolic and diastolic blood pressure Waist-to-hip ratio and weight (WHR)

General information

Reason for update

Completion of the sampling process and statistical analysis led us to update the recorded information of different sections of this trial in IRCT. As we have believed that this study might hold enormous potential for improving promising therapeutic agents to benefit patients who are suffering from various manifestations of endometriosis, especially endometrioma. Unfortunately, while updating the information related to the actual recruitment start/end dates, we noticed an inadvertent error in recording the expected recruitment start and end dates of the sampling, and a need has been felt on the imperative for transparency, accountability in order to fix that error and explain its causes to re-establish researchers' trust in this clinical trial's accuracy and reliability. All available evidence, including the date of approval of this clinical trial in the ethics committee of Tarbiat Modares University (IR.MODARES.REC.1398.142) and the date of entry of the researcher to the master's degree (1397-98 academic year) indicate an inadvertent error in the registration of this study and make the possibility of conducting this study in that time (before registration) unfeasible. We take full responsibility for the situation and all of patients' consents and questionnaire forms with detailed for the current study are available upon any requests. In addition, the simultaneous recruiting of patients and the coronavirus pandemic and its lockdown resulted in study participants' inaccessibility and trial personnel for in-person scheduled study visits and/or follow-up led to prolong sampling process and its postponement.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150905023897N4**
Registration date: **2019-11-09, 1398/08/18**
Registration timing: **prospective**

Last update: **2023-03-04, 1401/12/13**
Update count: **1**

Registration date

2019-11-09, 1398/08/18

Registrant information

Name
Dr. Shahideh Jahanian Sadatmahalleh
Name of organization / entity
Tarbiat Modares University
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-10-23, 1398/08/01
Expected recruitment end date
2020-05-21, 1399/03/01
Actual recruitment start date
2020-01-07, 1398/10/17
Actual recruitment end date
2021-01-04, 1399/10/15
Trial completion date
2021-04-12, 1400/01/23

Scientific title
To evaluate the effect of garlic tablet on metabolic syndrome in PCOS patients : A Randomized Double-blind Placebo-controlled Trial

Public title
To evaluate the effect of garlic tablet on metabolic syndrome in PCOS patients : A Randomized Double-blind Placebo-controlled Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People are willing to participate in the study fertility age between 15-49 years Iranian women no pregnancy have at least literacy for read and write no Mellitus Diabets according to primary FBS no chronic and coagulation disorders lack of consumption Anti lipids and Anti hypertensive and anti coagulative drugs no consuming garlic in a daily diet more than one cubit
Exclusion criteria:
People with drug side effects.Individuals unwilling to continue to participate in the study failure to comply with treatment protocol
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**
Actual sample size reached: **97**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly divided into two groups according to the blocking method and double blind
Blinding (investigator's opinion)
Double blinded
Blinding description
The researcher and patient will be unaware of the treatment and grouping of the study. For this purpose, Garlic tablets and placebo are coded by a research center. The lead researcher treats patients in a double-blind manner based on the drug package code. The code for the drug package is recorded on the personal information form, and the researcher who completes the information form will not be informed of the type of treatment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tarbiat Modares university
Street address
Jalal E Al Ahmad
City
Tehran
Province
Tehran
Postal code
۱۴۱۱۷۱۳۱۱۶
Approval date
2019-11-02, 1398/08/11
Ethics committee reference number
IR.MODARES.REC.1398.142

Health conditions studied

1

Description of health condition studied
Metabolic syndrome in PCOS patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

level of Triglyceride

Timepoint

First of study and 8 weeks after intervention

Method of measurement

blood biochemistry test

2

Description

level of cholesterol

Timepoint

First of study and 8 weeks after intervention

Method of measurement

blood biochemistry test

3

Description

blood level of HDL

Timepoint

First of study and 8 weeks after intervention

Method of measurement

blood biochemistry test

4

Description

blood level of FBS

Timepoint

First of study and 8 weeks after intervention

Method of measurement

blood biochemistry test

5

Description

level of systolic and diastolic blood pressure

Timepoint

First of study and 8 weeks after intervention

Method of measurement

Use of mercury barometer

6

Description

Waist to hip ratio

Timepoint

First of study and 8 weeks after intervention

Method of measurement

Use of meter

Secondary outcomes

1

Description

Level of CRP

Timepoint

First of study and 8 weeks after intervention

Method of measurement

Blood biochemistry test

2

Description

menstrual dysfunction such as: Oligomenorrhea and amenorrhea

Timepoint

First of study and 8 weeks after intervention

Method of measurement

patient statements

3

Description

clinical hyperandrogenemia

Timepoint

First of study and 8 weeks after intervention

Method of measurement

Blood biochemistry test and clinical symptom

4

Description

Ultrasound view of the ovaries

Timepoint

First of study and 8 weeks after intervention

Method of measurement

Use of ultrasound

5

Description

sexual function

Timepoint

First of study and 8 weeks after intervention

Method of measurement

FSFI questionnaire

6

Description

Quality Of life

Timepoint

First of study and 8 weeks after intervention

Method of measurement

MPCOSQ questionnaire

Intervention groups

1

Description

Intervention group: Treatment by garlic tab 500 mg

Category

Treatment - Drugs

2

Description

Control group: treatment by placebo of garlic tab

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Arash hospital

Full name of responsible person
Shahideh Jahanian Sadatmahalleh

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Sponsors / Funding sources

1

Sponsor

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pres@modares.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tarbiat modares University

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
Tarbiat modares University

Full name of responsible person
Shahideh Jahanian Sadatmahalleh

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
Information on the main outcome of the study

When the data will become available and for how long
1400

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Use for further research in the future

From where data/document is obtainable
Email Addressing Responsible for Study

What processes are involved for a request to access data/document
Submit a request to study and follow up

Comments