

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of garlic tablet on mood and physical disorder in premenstrual period

Protocol summary

Study aim

The effect of garlic tablet on mood and physical disorder in premenstrual period

Design

After completion of the initial questionnaire, the dormitory students completed the PSST questionnaire and their satisfaction. This study is a double-blind randomized clinical trial with parallel groups. The appropriate sample size (120 people) is grouped into two groups based on randomly generated computer sequences and each one receives a code.

Settings and conduct

Investigator and participant are unaware of drug content. Drugs are required for three daily cycles, a PSST questionnaire, and a form of side effects in the first study. Each of these three is given to each sample in Ahmadi's health center, and they are asked to complete each cycle on the seventh to tenth day of each cycle.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ready to participate in the study
Women 18 to 35 years old Regular menstruation with cycle 21 to 35 days Medium PMS in questionnaire
Non-inclusion criteria: Pregnancy and lactation Physical illnesses like thyroid disease or anemia Mental illness with medication Use of hormones, cigarettes, alcohol, anticoagulants and supplements Stressful accidents from three months ago PMS treatment since two months ago

Intervention groups

Intervention group: 400 milligrams of garlic Control group: Placebo tablets containing starch

Main outcome variables

Premenstrual syndrome Age Height Weight BMI Anger Anxiety Crying Depressed mood Reducing interest in job activity Reducing interest in home-based activity Reducing interest in social activity Difficulty concentrating Fatigue Overeating insomnia Sweaty Feelings Breast pain Headache Dizziness Nausea Flatulence Weight Gain The amount of bleeding Duration of bleeding Cycle length

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180311039038N1**

Registration date: **2018-03-25, 1397/01/05**

Registration timing: **prospective**

Last update: **2018-03-25, 1397/01/05**

Update count: **0**

Registration date

2018-03-25, 1397/01/05

Registrant information

Name

fatemeh jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4426 8960

Email address

f_jafari@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of garlic tablet on mood and physical disorder in premenstrual period

Public title

The effect of garlic on the treatment of premenstrual dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ready to participate in the study Women aged 18 to 35 years old Regular menstruation with a length of 21 to 35 days from six months ago Proof of PMS moderate in the questionnaire

Exclusion criteria:

Pregnancy and lactation Physical illnesses like thyroid disease or anemia in history or paraclinic mental illness with taking medication Use of hormonal drugs, cigarettes, alcohol, anticoagulants and supplements Stressful events from the three months before the study Drug use for PMS two months before the study

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are grouped into two groups A and B, based on random sequences generated by computer software. Each patient receives a code. One drug group is being treated and one placebo group

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients receive encoded medication without knowing that they are in the intervention or control group. The researcher does not know the pharmaceutical content of the samples

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Room 605, 6th floor, central building of Tehran University of Medical Sciences, Keshavarz Blvd and Ghodss St., Tehran

City

Tehran

Province

Tehran

Postal code

1463815763

Approval date

2018-02-27, 1396/12/08

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4670

Health conditions studied

1

Description of health condition studied

Premenstrual dysfunction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of garlic on premenstrual dysfunction

Timepoint

At the beginning of the study and at the beginning of each cycle after the intervention for three cycles of menstruation

Method of measurement

Questionnaire

Secondary outcomes

1

Description

The effect of garlic on menstrual pattern

Timepoint

At the beginning of the study and at the start of each cycle after the intervention for three menstrual cycles

Method of measurement

Questionnaire

Intervention groups

1

Description

Category

empty

2

Description

Intervention group: Garlic Tablets is 400 mg of Dineh Pharmaceutical Company, which is available in Iran's pharmaceutical market and consumes a daily amount of three consecutive cycles.

Category

Treatment - Other

3

Description

Control group: Placebo pill contains starch powder that is similar in appearance to the garlic pill and is prepared by the same company and consumed in the same way.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Student Dormitory in Nasibe in Tehran

Full name of responsible person

Marzieh Baghestani

Street address

Nasiba Pardis in Tehran, Nsiba St. Blvd. Marzardan, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Sahraeian

Street address

Central Building of Tehran University of Medical Sciences, Keshavarz Blvd. and Qods St., Tehran

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research@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Jafari

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Health Center Ahmadiye, Northern sarparast St, Taleghani St., Tehran

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available