Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Investigating the effect of zinc use on medical students living in the dormitories of Shahid Beheshti University of Medical Sciences with premenstrual syndrome in the Faculty of Medicine

Protocol summary

Study aim
Determining the effect of zinc supplementation on psychological and physical symptoms caused by premenstrual syndrome

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 200 patients. The rand function of Excel software was used for randomization.

Settings and conduct
In this study, we intend to measure the effect of zinc use on psychological and somatic symptoms of premenstrual syndrome in a randomized and double-blind clinical trial. For this purpose, first, 200 interns and interns of Shahid Beheshti University of Medical Sciences, who are single and live in the student dormitory, are randomly called to participate in the study.

Participants/Inclusion and exclusion criteria
Age between 20-35 years / history of regular menses (at least in the last 6 months each cycle 21-35 days and the amount of bleeding is not severe and it has been bleeding for less than 7 days) / BMI between 19.8 to 26/ diagnosis of premenstrual syndrome based on PSST questionnaire People who have any chronic disease or psychiatric disease caused by severe PMS, receive psychiatric drugs, hormones, Supplements at the time of study or 6 months before, smokers and vegetarian diet, suspected pregnancy, desire to Those who are pregnant or currently breastfeeding will not be included in the study

Intervention groups
The use of 220 mg zinc gluconate tablets in the intervention group and placebo in the control group

Main outcome variables
Psychological and physical symptoms caused by premenstrual syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221127056632N1**
Registration date: **2023-02-05, 1401/11/16**
Registration timing: **prospective**

Last update: **2023-02-05, 1401/11/16**
Update count: **0**

Registration date
2023-02-05, 1401/11/16

Registrant information

Name
Samira Zallaghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5506 5547

Email address
samira.z1399@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-06-05, 1402/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of zinc use on medical students living in the dormitories of Shahid Beheshti University of Medical Sciences with premenstrual syndrome in the Faculty of Medicine

Public title
Zinc supplemnt in premenstruation syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 20-35 years History of regular menses at least in the last 6 months (each cycle lasts 21-35 days and the amount of bleeding is not severe and has less than 7 days of bleeding) Body mass index between 19.8 and 26 Diagnosis of premenstrual syndrome based on PSST questionnaire

Exclusion criteria:
Any chronic illness or psychiatric illness caused by severe PMS Receiving hormonal psychiatric drugs, supplements at the time of the study or 6 months before Smokers and vegetarians Suspected pregnancy, desire to become pregnant, current breastfeeding

Age
From **18 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, individual In this way, after collecting the initial questionnaires, by a person outside the study, the owner of each questionnaire is assigned a 4-digit code that starts from 1000 consecutively. Then people with an even code enter the control group with placebo and people with an odd code enter the group supplemented with zinc.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is double-blind and the participants and the researcher who dispenses the drug do not know who belongs to the control or intervention group. In this study, with the coordination of the pharmaceutical company, the placebo and the drug have been tried to be completely similar.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committee of School of Medicine - Shahid Beheshti University of Medical Sciences

Street address
shahid beheshti medical university, koodakiar Ave., Arabi street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2022-11-29, 1401/09/08

Ethics committee reference number
IR.SBMU.MSP.REC.1401.439

Health conditions studied

1

Description of health condition studied
Premenstrual tension syndrome

ICD-10 code
N94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Physical and psychological symptoms of premenstrual syndrome

Timepoint
At the beginning of the study (when sampling and before the start of the intervention) and 3 months after the start of the intervention

Method of measurement
Premenstrual Symptoms Screening Tool questionaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Zinc supplement users-These people are 100 people who were randomly selected and will be

treated with oral zinc supplements (produced by RouaDaru pharmaceutical company and with a dose of 30 mg) for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: placebo users-According to our order to Roz Daru Company, similar to supplement pills

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdie Hospital

Full name of responsible person

Samira Zalaghi

Street address

Shush Square - Fedayian Islam St. - Shishagar Khane Alley - Shahid Rajab Nia St

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1185817311

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Email

mahdiyeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zaraghi

Street address

Shahid beheshti medical university, Koodakiar Ave, Arabi street, Velenjak

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Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Samira Zallaghi

Position

Medical Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information related to the main outcome, including the PSST test score, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

All researchers working in academic, scientific and industrial institutions can apply to receive information.

Under which criteria data/document could be used

The data of this study can be used for systematic review studies and meta-analysis after the publication of the article.

From where data/document is obtainable

Applicants need to send an email to the main organizer of the project at samira.z1399@gmail.com in English.

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

After sending an email in English to the above address, the applicant can access the data after two working weeks.

Comments