

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 supplement 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 questionnaire

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

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Email

mahdiyeh_hospital@sbm.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

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

Mpajouhesh@sbm.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

Street address

Valiasr street, before Tajrish square, Sarshar avenue, No12

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 5506 5547

Fax**Email**

samira.z1399@gmail.com

Person responsible for scientific 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

Street address

Valiasr street, before Tajrish square, Sarshar avenue, No12

City

Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 5506 5547
Fax
Email
samira.z1399@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Samira Zalaghi
Position
Medical Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Valiasr street, before Tajrish square, Sarshar avenue,
No12
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
samira.z1399@gmail.com

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