

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The Effect of zinc supplementation versus placebo on the improvement of clinical symptoms among students with premenstrual syndrome: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of zinc supplementation versus placebo on the improvement of clinical symptoms among students with premenstrual syndrome

Design

This is a double-blind randomized clinical trial, phase II, in which 86 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible students with premenstrual syndrome residents of the dormitory of Hamadan University of Medical Sciences during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years, Premenstrual syndrome, Student resident of the dormitory of Hamadan University of Medical Sciences, Exclusion criteria: Malnutrition, Sepsis, Acute meningitis, Unstable hemodynamic status, Diarrhea, Mood or psychological disorder

Intervention groups

Intervention group: Zinc sulfate capsule 220 mg (manufactured by Hakimian Daru Pharmaceutical Co.) daily for three months Control group: Placebo capsule (manufactured by Hakimian Daru Pharmaceutical Co.) daily for three months

Main outcome variables

Primary outcome: The severity of clinical symptoms of premenstrual symptoms, Secondary outcome: The severity of pain, the severity of hemorrhage, the duration of hemorrhage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N347**

Registration date: **2020-03-14, 1398/12/24**

Registration timing: **prospective**

Last update: **2020-03-14, 1398/12/24**

Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of zinc supplementation versus placebo on the improvement of clinical symptoms among students with premenstrual syndrome: a double-blind randomized clinical trial

Public title

The Effect of zinc supplementation versus placebo on the improvement of clinical symptoms among students with premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 35 years, Premenstrual syndrome, Student resident of dormitory of Hamadan University of Medical Sciences,

Exclusion criteria:

Malnutrition, Sepsis, Acute meningitis, Unstable hemodynamic status, Diarrhea, Mood or psychological disorder

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs will be given in coded envelopes. The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-03-07, 1398/12/17

Ethics committee reference number

IR.UMSHA.REC.1398.1080

Health conditions studied**1****Description of health condition studied**

Premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes**1****Description**

Severity of clinical symptoms of premenstrual symptoms

Timepoint

Before the intervention and then after first, second, third, and sixth months after the intervention

Method of measurement

Using Premenstrual Symptoms Screening Tool (PSST) questionnaire

Secondary outcomes**1****Description**

The severity of pain

Timepoint

Before the intervention and then after first, second, third, and sixth months after the intervention

Method of measurement

Using Visual analog Scale (VAS)

2

Description

The severity of hemorrhage

Timepoint

Before the intervention and then after first, second, third, and sixth months after the intervention

Method of measurement

By taking history

3

Description

The duration of hemorrhage

Timepoint

Before the intervention and then after first, second, third, and sixth months after the intervention

Method of measurement

By taking history

Intervention groups

1

Description

Intervention group: Zinc sulfate capsule 220 mg (manufactured by Hakimian Daru Pharmaceutical Co.) daily for three months

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule (manufactured by Hakimian Daru Pharmaceutical Co.) daily for three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dormitory of Hamadan University of Medical Sciences

Full name of responsible person

Dr Mayam Ahmadi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

ahmadi_1011@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Mayam Ahmadi

Position

Resident of Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

ahmadi_1011@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Shahedeh Khansari

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

dr_sh_kh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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