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

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Iran (Islamic Republic of)

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**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 Hakiman Daru Pharmaceutical Co.) daily for three months
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Placebo capsule (manufactured by Hakiman 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
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## Sponsors / Funding sources

**1**

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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**
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Hamedan University of Medical Sciences
**Full name of responsible person**
Dr Mayam Ahmadi
**Position**
Resident of Gynecology
**Latest degree**
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**Other areas of specialty/work**
Gynecology and Obstetrics
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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