

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### The effect of zinc supplementation on psychological and physical symptoms, sleep quality, quality of life, total antioxidant capacity, serum concentrations of Brain derived neurotrophic factor and high-sensitivity C-reactive protein in young women with premenstrual syndrome

#### Protocol summary

##### Study aim

we aim to explore the effects of zinc supplementation PMS patients.

##### Design

This is a parallel double-blind, randomized, placebo controlled clinical trial.

##### Settings and conduct

This study has 2 phases. In the first phase young women will be ask to fill the 30 item checklist to temporary diagnosis of the PMS. Women with PMS, will be ask to fill the beck depression and anxiety questionnaires to make sure the are not depressed or have anxiety. In the second phase of study, all the eligible women will record their symptoms with daily record questionnaire for 2 menstrual cycles before the intervention. After 2 cycles, participants who definitely diagnose to have PMS will allocate into 2 groups of 30 subjects, one group will be the intervention and the other group will be the control group. All participants will be assess in a week before menses before and after the intervention. Along with the second package of tablets, subjects will provide with the same daily record questionnaire as before to record their symptoms during next 2 menstrual cycles.

##### Participants/Inclusion and exclusion criteria

having PMS, age between 18,30, BMI between 18.5-24.9, single healthy young women with regular menstrual cycle of 21-35 days, not being depressed or having anxiety, not taking any oral contraceptives or any medications and zinc supplement in past 3 months, not exercising regularly.

##### Intervention groups

Intervention group will take zinc gluconate tablets containing 30mg elemental zinc, and control group will take placebo tablets with identical appearance containing starch for 12 weeks.

##### Main outcome variables

psychological and physical PMS symptoms, sleep quality, quality of life serum levels of BDNF (Brain derived neurotrophic factor), hs-CRP (High-sensitivity C-reactive Protein), TAC ( High-sensitivity C-reactive Protein)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180215038738N1**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

##### Registration date

2018-05-29, 1397/03/08

##### Registrant information

##### Name

fatemeh jafari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3234 4866

##### Email address

f.jafari@nutr.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2018-06-20, 1397/03/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
The effect of zinc supplementation on psychological and physical symptoms, sleep quality, quality of life, total antioxidant capacity, serum concentrations of Brain derived neurotrophic factor and high-sensitivity C-reactive protein in young women with premenstrual syndrome  
**Public title**  
The effect of zinc supplementation on young women with premenstrual syndrome  
**Purpose**  
Treatment  
**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
18.5 < Body mass index (BMI) < 25 single women regular menstrual cycle of 21-35 days  
**Exclusion criteria:**  
taking any medications containing estrogen and progesterone taking zinc supplement in past 3 months exercising regularly being depressed or having anxiety  
**Age**  
From **18 years** old to **30 years** old  
**Gender**  
Female  
**Phase**  
3  
**Groups that have been masked**  

- Participant
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **60**  
**Randomization (investigator's opinion)**  
Randomized  
**Randomization description**  
Subjects will be allocating into intervention or placebo group by permuted block randomization method.  
**Blinding (investigator's opinion)**  
Double blinded  
**Blinding description**  
zinc supplement and placebo will have Identical appearance  
**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**  
  
**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan university of Medical Sciences

##### Street address

Isfahan University of Medical Sciences, Hezar Jirib Street, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Approval date

2017-06-20, 1396/03/30

##### Ethics committee reference number

IR.MUI.REC.1396.3.247

## 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

physical symptoms of young women with premenstrual syndrome

#### Timepoint

before and 12 weeks after the start of intervention

#### Method of measurement

daily record questionnaire

### 2

#### Description

psychological symptoms of young women with premenstrual syndrome

#### Timepoint

before and 12 weeks after the start of intervention

#### Method of measurement

daily record questionnaire

### 3

#### Description

total antioxidant capacity

#### Timepoint

before and 12 weeks after the start of intervention

#### Method of measurement

Laboratory analysis ( blood test)

#### 4

##### **Description**

serum concentrations of Brain derived neurotrophic factor

##### **Timepoint**

before and 12 weeks after the start of intervention

##### **Method of measurement**

Laboratory analysis ( blood test)

#### 5

##### **Description**

serum concentrations of high-sensitivity C-reactive protein

##### **Timepoint**

before and 12 weeks after the start of intervention

##### **Method of measurement**

Laboratory analysis ( blood test)

#### 6

##### **Description**

serum concentrations of zinc

##### **Timepoint**

before and 12 weeks after the start of intervention

##### **Method of measurement**

Laboratory analysis ( blood test)

## **Secondary outcomes**

#### 1

##### **Description**

sleep quality

##### **Timepoint**

before and 12 weeks after the start of intervention

##### **Method of measurement**

pittsburgh sleep quality index

#### 2

##### **Description**

quality of life

##### **Timepoint**

before and 12 weeks after the start of intervention

##### **Method of measurement**

World Health Organization Quality Of Life questionnaire

## **Intervention groups**

#### 1

##### **Description**

Intervention group: Supplementation of zinc gluconate including 30 mg of elemental zinc (Dine Iran Pharmaceutical Company ),every day 1 supplement, 12 weeks

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

Control group: placebo (Dine Iran Pharmaceutical Company ), every day 1 supplement, 12 weeks

##### **Category**

Placebo

## **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Isfahan University Dormitories

###### **Full name of responsible person**

DR. Reza Amani

###### **Street address**

Isfahan University and Isfahan University of Medical Sciences dormitories complex, Hezar Jerib Street, Isfahan

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8135798111

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## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Esfahan University of Medical Sciences

###### **Full name of responsible person**

Dr.Amirmansour Alavi

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am.alavi@nutr.mui.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Esfahan 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**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Jafari  
**Position**  
MSc student of Nutrition  
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Bachelor  
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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

Yes - There is 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

### Title and more details about the data/document

not decided yet.

### When the data will become available and for how long

not decided yet.

### To whom data/document is available

not decided yet.

**Under which criteria data/document could be used**

not decided yet.

**From where data/document is obtainable**

not decided yet.

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

not decided yet.

**Comments**