Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Zinc sulfate Consumption In Premenstrual Syndrome: Measuring Its Effects on Quality of Life Using the PSST& SF12 Questionnairs

Protocol summary

Summary

Background: Premenstrual syndrome (PMS) is among the most prevalent disorders of the fertility ages. It affects the individual's activities in family and society. Regarding its problems and difficulties, the related medical interventions are considered of great importance. Objective: The aim of this research is considering the effect of using Zinc sulphate on the life quality of the patients suffering from premenstrual syndrome. Method: The research was conducted in two stages. The first stage related to specifying and recognizing the people suffering from medium to severe PMS. The second stage was the blind technique randomize clinical. At the first stage, some female students of the Tehran and Tarbiat Modares Universities residing dormitoreis were selected randomly and filled 530 PSST questionnaires (PSST questionnaire psychometrics was conducted in this case for the first time); the PMS patients were recognized. At the second stage among 275 patients, 142 samples qualified for trial. They entered the study after signing the written consent form; they classified in two groups of control and test equally. At last data related to 130 samples were analyzed statistically. The samples received Zinc sulphate and Plasbo in three menstrual period and reported the results at the end of each period. They also filled SF12 questionnaire i.e. a summary form of SF36 life quality (which is standardized in Iran). It has restricted to two physical and mental aspects. Key Words: Premenstrual syndrome, zinc sulphate, life quality.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809232852N1**
Registration date: **2010-06-06, 1389/03/16**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2010-06-06, 1389/03/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University Faculity of Medical Sciences

Expected recruitment start date

2009-01-02, 1387/10/13

Expected recruitment end date

2010-01-07, 1388/10/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Zinc sulfate Consumption In Premenstrual Syndrome: Measuring Its Effects on Quality of Life Using the PSST& SF12 Questionnairs

Public title

Zinc sulfate Consumption In Premenstrual Syndrome: Measuring Its Effects on Quality of Life Using the PSST& SF12 Questionnairs

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria were: being single, suffering from moderate to severe PMS based on PSST questionnaires, age between 20 and 35 year with regular and normal menstruation (menstrual cycle 22 to 35 days and duration of bleeding 3 to 7 days), Normal BMI (26-19) Exclusion criteria: cardiovascular, pulmonary, renal, diabetes, liver, gastrointestinal, gynecological, and thromboembolic diseases, including chronic migraines, mental illness, taking any medication, and being under severe stress such as death of loved ones etc in the past three months, smoking and alcohol consumption, and consuming too much or too little food based on the questionnaire 1
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tarbiat Modarres University
Street address
Tehran, Jalal Al Ahmad St., Chamran Highway Intersection
City
Tehran
Postal code
Approval date
empty
Ethics committee reference number
15070892

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
Symptoms of Premenstrual Syndrome
Timepoint
Before intervention, the first month, second month and third month after the intervention
Method of measurement
Psst Questionnaire

2

Description
Quality of life
Timepoint
Before intervention, the first month, second month and third month
Method of measurement
sf12 Questionnaire

Secondary outcomes

1

Description
Side effects, including gastrointestinal
Timepoint
After 3 month
Method of measurement
Questionnaire

2

Description
Tendency for future medication use
Timepoint
After 3 month
Method of measurement
Questionnaire

3

Description
Dysmenorrhea
Timepoint
After 3 month
Method of measurement
Questionnaire

Intervention groups

1

Description
Intrvention group Zinc sulfate
Category
Treatment - Drugs

2

Description
Control group Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tarbiat Modares University
Full name of responsible person
Shiva Siahbazi
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Tehran university
Full name of responsible person
Street address
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tarbiat Modares Univresity
Full name of responsible person
Dr Lida Moghaddam
Street address
Tehran Tarbiat Modares Univrecity-Faculty of Medical Sciences 5 Midwifery group
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat Modares Univresity
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Tarbiat Modares University
Full name of responsible person

Shiva Siahbazi

Position

Other areas of specialty/work

Street address

City

TEHRAN

Postal code

Phone

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty