

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

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

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

Name

Shiva Siahbbazi

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8801 1001

Email address

siahbbazi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University Faculty 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 Questionnaires

Public title

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

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

Tehran

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

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Shiva Siahbazi

Position

Master of Sciences of Midwifery

Other areas of specialty/work

Street address

Tehran Tarbiat Modares University

City

Tehran

Postal code

Phone

+98 21 6603 5351

Fax

Email

SIAHBAZI@Modares.ac.ir;shiva_siahbazi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares Univesity

Full name of responsible person

Shiva Siahbazi

Position

Master Of Sciences In Midwifery

Other areas of specialty/work

Street address

Tehran -Tarbiat Modares Univesity-Department of Midwifery

City

Tehran

Postal code

Phone

+98 21 6603 5351

Fax

Email

SIAHBAZI@Modares.ac.ir;shiva_siahbazi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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