Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The combined effect of vitamin D and Zinc on symptoms of depression, anxiety, premenstrual syndrome (PMS) and Total antioxidant capacity (TAC) in people with premenstrual syndrome (PMS): a randomized, Three-blind clinical trial

Protocol summary

Study aim
Determining the effect of vitamin D and zinc supplementation on depression and anxiety, symptoms related to premenstrual syndrome (PMS) and Total Antioxidant Capacity (TAC) in people with PMS

Design
A clinical ، three-blind, randomized, two arm parallel group, placebo-controlled trial on96 people with PMS. Randomization is done by software available on the Internet.

Settings and conduct
This study was a randomized, Three -blind, placebo-controlled trial. 96women (18–30 years) with premenstrual syndrome diagnosed according PMS questionnaire were randomly assigned to receive either 30-mg zinc gluconate and 2000IU vitamin D (group 1; n = 48) and/or placebo (group 2; n = 48) for 8 weeks. Premenstrual syndrome symptoms, total antioxidant capacity, depression, anxiety were measured at study baseline and after 8weeks intervention. In this study The researcher, the patients and the analyzer are blinded.

Participants/Inclusion and exclusion criteria
Single women with a regular menstrual cycle between 24 and 35 days BMI of participating women between 18.5 and 24.9 Not doing sports professionally Not taking any contraceptive pills, not taking other drugs Not receiving vitamin D and zinc supplements 3 months before the intervention Not having any history of acute and chronic diseases and gynecological disorders and psychological diseases

Intervention groups
The intervention group will receive a daily vitamin D supplement (2000 IU) and zinc supplement (zinc gluconate tablets containing 30 mg of elemental zinc) for 8 weeks. The control group will receive placebo tablets (completely similar capsules that contain oral paraffin In terms of appearance, color, smell, size and packaging, it is completely similar to vitamin D3, and they will use placebo tablets containing starch for zinc supplementation

Main outcome variables
Depression, Anxiety, Premenstrual Syndrome (PMS), Total antioxidant capacity (TAC)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090901002394N47**
Registration date: **2023-06-27, 1402/04/06**
Registration timing: **prospective**

Last update: **2023-06-27, 1402/04/06**
Update count: **0**

Registration date
2023-06-27, 1402/04/06

Registrant information

Name
Shima Jazayeri
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8670 4805
Email address
sjazayeri@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-01, 1402/04/10
Expected recruitment end date
2024-06-30, 1403/04/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The combined effect of vitamin D and Zinc on symptoms of depression, anxiety, premenstrual syndrome (PMS) and Total antioxidant capacity (TAC) in people with premenstrual syndrome (PMS): a randomized, Three-blind clinical trial

Public title
The combined effect of vitamin D and zinc on premenstrual syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Single women with a regular menstrual cycle between 24 and 35 days The suitable age for the study is 18-30 years old BMI of the studied women is between 18.5 and 24.9 Not taking any contraceptive pills Not taking anti-inflammatory, anti-depressant and psychotic drugs Not doing sports professionally Not taking vitamin D and zinc supplements for 3 months before starting the study Willingness, satisfaction and ability to carry out and complete the study and cooperate with the research
Exclusion criteria:
Being married Having vitamin D deficiency Suffering from an endocrine disorder such as thyroid failure, polycystic ovary syndrome and diabetes mellitus History of gynecological disorders History of autoimmune diseases Suffering from chronic and acute diseases (acute or chronic kidney failure, acute or chronic liver failure, chronic inflammatory disease or any known malignancy) Having irregular menstrual cycles (Less than 24 days and more than 35) Having stress caused by the death of relatives, surgery or marriage in the previous three months History of psychiatric diseases
Age
From **18 years** old to **30 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize the samples, first, a list of 96 items is generated by the software available on the internet into two groups of 48 items that are separated by the letters A and B, and this list is provided to the researcher, and the eligible samples are referred to groups A and B are allocated. The manufacturer of the placebo is asked to put one of the labels A or B on the drug and the other on the placebo by throwing a coin and keep this confidential until the end of the data analysis, and therefore the drugs with one of the letters A or B and placebos are indicated by another letter. According to the randomization table below, the researcher will distribute the drug and placebo according to the order of reference of the samples from packages A or B, so this study will be a three-blind study, that is; The patient, the researcher and the analyst will not be aware of the type of packages received by the samples until the end of the data analysis
Blinding (investigator's opinion)
Triple blinded
Blinding description
The manufacturer of the placebo is asked to put one of the labels A or B on the drug and the other on the placebo by throwing a coin and keep this confidential until the end of the data analysis, and therefore the drugs with one of the letters A or B and placebos are indicated by another letter. According to the randomization table below, the researcher will distribute the drug and placebo according to the order of reference of the samples from packages A or B, so this study will be a three-blind study, that is; The patient, the researcher and the analyst will not be aware of the type of packages received by the samples until the end of the data analysis
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran university of medical Sciences
Street address
Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date

2023-05-24, 1402/03/03

Ethics committee reference number

IR.IUMS.REC.1402.143

Health conditions studied

1

Description of health condition studied

Premenstrual Syndrome (PMS)

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

Depression score in Beck's Depression Inventory

Timepoint

At baseline and after8 weeks

Method of measurement

Beck's Depression Inventory

2

Description

Depression score in Beck Anxiety Inventory

Timepoint

At baseline and after8 weeks

Method of measurement

Beck Anxiety Inventory

3

Description

the score of The premenstural symptoms screening tool (PSST)

Timepoint

At baseline and after8 weeks

Method of measurement

The premenstural symptoms screening tool (PSST)

4

Description

The levels of total antioxidant capacity

Timepoint

At baseline and after8 weeks

Method of measurement

ELISA Kit

Secondary outcomes

1

Description

Weight

Timepoint

At baseline and after8 weeks

Method of measurement

Scale

2

Description

Body mass index

Timepoint

At baseline and after8 weeks

Method of measurement

Calculation

3

Description

Waist circumference

Timepoint

At baseline and after8 weeks

Method of measurement

Measuring tape

Intervention groups

1

Description

intervention group : In this group, 48 people with premenstrual syndrome take a vitamin D supplement of 2000 units and a zinc supplement in the form of zinc gluconate tablets containing 30 mg of elemental zinc every day for up to 8 weeks. These supplements are made by jalinous company.

Category

Treatment - Other

2

Description

Control group: In this group, there are 48 people receiving placebo who take capsules completely similar to the original supplements for 8 weeks.The manufactured placebo for vitamin D includes edible paraffin, which is completely similar to vitamin D3 in terms of appearance, color, smell, size, and packaging, and also the placebo for zinc supplementation contains starch. Placebos are made by Galenus company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences

Full name of responsible person

Zahra Esmailpour

Street address

Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran

City

Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 1021
Email
adminsite@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
Street address
Iran University of Medical Sciences, 5th floor of the central headquarters, Hemat Highway, next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 5533
Fax
+98 21 8670 2503
Email
falak.r@iums.ac.ir
Web page address
https://vcr.iums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Zahra Esmailpour
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Ibn Sina Student Dormitory, Behdad Shayeg, South Amir Kabir St., end of Jalal El Ahmad Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1461614745
Phone
+98 21 5526 1111
Email
esmailpour.zahraa@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Zahra Esmailpour
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Ibn Sina Student Dormitory, Behdad Shayeg, South Amir Kabir St., end of Jalal El Ahmad Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1461614745
Phone
+98 21 5526 1111
Email
esmailpour.zahraa@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Zahra Esmailpour
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition

Street address
Ibn Sina Student Dormitory, Behdad Shayeg, South Amir Kabir St., end of Jalal El Ahmad Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1461614745
Phone
+98 21 5526 1111
Email
esmailpour.zahraa1997@gmail.com

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