

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Survey the effect of vitamin D3 tablet intake, positivism group consulting with changing in life style in the treatment of premenstrual syndrome in women

Protocol summary

Study aim

Determining the effect of vitamin D3 and positive group counseling on lifestyle changes in premenstrual women of reproductive age

Design

A parallel clinical trial with a parallel control group, randomized

Settings and conduct

Random sampling is performed on women of reproductive age in Arsanjan for all groups of premenstrual syndrome before the study, at 6 weeks and 10 weeks after the intervention. Satisfaction with intervention methods is complete in 6 and 10 weeks.

Participants/Inclusion and exclusion criteria

Criteria for the study included participants' self-report of no history of treatment or lack of contraceptive pills, any herbal remedies, or pre-menopausal, drug-treated; having two menstrual cycle after a year. Criteria for exit are: stressful events, such as the death of relatives, parental separation, accidents, failure to attend two or more meetings.

Intervention groups

In the intervention group with positive group-based method, 6 group sessions are held once a week for 90 minutes in online counseling sessions because of covid 19 pandemic . Intervention group consuming vitamin D3, met criteria and after determining 25-hydroxy vitamin D level, subjects with serum levels less than 30 ng / ml will be enrolled. Each person is given 6 doses of vitamin D3, 50,000 units to be taken 1 doses per week for 6 weeks. D is given 50,000 units and re-measured at the end of the intervention For lifestyle change groups, sessions on appropriate physical activity, weight and fitness control, healthy eating, menstrual health, tobacco harm and familiarity with early detection methods of common female cancer (breast and cervical cancer) and during 6 The meeting will be held in 6 online sessions.

Main outcome variables

1-Premenstrual syndrome, 2- Satisfaction with intervention methods

General information

Reason for update

1- Registration of the end of the trial, 2- Correction of the intervention, which was registered in combination of three face-to-face sessions three online sessions, but because of covid 19 pandemic all 6 sessions in 3 groups were held online. 3- As you can see in intervention in intervention section and other parts of trial PMS and satisfaction with intervention methods were mentioned as main outcome variables but in main outcome variables box only study applicable aim was mentioned, so main outcome variables should be corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191231045967N1**
Registration date: **2020-02-11, 1398/11/22**
Registration timing: **prospective**

Last update: **2021-06-15, 1400/03/25**

Update count: **1**

Registration date

2020-02-11, 1398/11/22

Registrant information

Name

Maryam Mahmoodi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2020-02-20, 1398/12/01

Expected recruitment end date

2020-04-02, 1399/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of vitamin D3 tablet intake, positivism group consulting with changing in life style in the treatment of premenstrual syndrome in women

Public title

Determining the effect of vitamin D3 and positive group counseling with lifestyle changes in premenstrual women of reproductive age

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being a resident of Rafsanjan city No history of treatment or depression or anxiety disorder No history of treatment or eating disorder No history of treatment or anemia disorder No history of treatment or thyroid disorder No history of treatment or presence of diabetes Not taking birth control pills for medical reasons Not taking any herbal medicine or medicine that affects premenstrual syndrome Lack of treatment with psychiatric drugs and other non-pharmacological methods Lack of treatment with other non-medicinal methods Having two consecutive menstrual cycles a year with symptoms of premenstrual syndrome with at least five symptoms, one of which are mood disorders, which begin in the second half of the menstrual cycle and improve after menstruation, according to the self-report. Having at least a 30% increase in symptom severity within 5 days before menstruation based on the PMS Willingness to continue collaborating on tasks for 6 weeks Failure to participate in another related study until the expiration of the current study

Exclusion criteria:

Severe form of premenstrual syndrome with a score of 35 and more from the premenstrual syndrome calendar

Age

From 20 years old to 40 years old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 84

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random sampling In this way, we first obtain the list of all members, then assign a score to each of them, and select the required number using the random number table.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Fars, Arsanjan city, Imam Khomeini town, Modarres Alley 4

City

yazd

Province

Yazd

Postal code

7376187999

Approval date

2019-12-31, 1398/10/10

Ethics committee reference number

IR.SSU.REC.1398.157

Health conditions studied**1****Description of health condition studied**

Women's premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes**1****Description**

1-Mean premenstrual syndrome scores, 2- Satisfaction with intervention methods

Timepoint

1-For premenstrual syndrome before the intervention, complete the sixth week of the intervention and finish

the tenth week.2- At the end of 6 and 10 weeks

Method of measurement

1-Premenstrual Syndrome Screening Tool , 2-Satisfaction tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group consuming vitamin D3, with a criterion and after determining 25 hydroxyvitamin D level, subjects with serum level less than 30 ng / ml will be included in the study. Each person is given 6 capsules of vitamin D 50000, D3 to take 1 dose per week for 6 weeks. After 6 weeks of administration and determination of 25- γ hydroxytryptamine serum level, the physician is instructed to take one vitamin D within 4 weeks. 50,000 units manufactured by the pharmaceutical company are disposed of and re-measured at the end of the intervention. The premenstrual syndrome form is completed before the study, at 6 weeks and 10 weeks after the intervention. Satisfaction with intervention methods is assessed in weeks 6 and 10.

Category

Treatment - Drugs

2

Description

Intervention group: In the intervention group, 6 group sessions will be held online because of covid 19 pandemic once a week for 90 minutes in a positive-group group. After selecting the women for the meetings, we select the days of the two groups' meetings as suggested by the women on two different days of the week so that the two groups receiving the consultation do not interact with each other. , Second session, gratitude meeting, third session, constructive active response, fourth session, counting blessings, fifth session, sense of taste, sixth session, preservation of therapeutic effects. Pre-menstrual syndrome form before study, 6 weeks intervention and Week 10 was completed after the intervention. Satisfaction with intervention method is assessed in weeks 6 and 10.

Category

Behavior

3

Description

Control group: Lifestyle group sessions on appropriate physical activity, weight and fitness control, healthy eating, menstrual mental health, tobacco harm and familiarity with early detection methods of common female cancer (breast and cervical cancer) and during 6 sessions for 2 groups are held in two days, 6 sessions online because of covid 19 pandemic. The premenstrual

syndrome form is completed before the study, at 6 weeks and 10 weeks after the intervention. Satisfaction with intervention method is assessed in weeks 6 and 10.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Arsanjan Health Center

Full name of responsible person

Dr. Ismail Eskandari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Mirjali

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Fars province, Arsanjan, Imam Khomeini town

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

50

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Dr. Tahmineh Faraj Khoda

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Other areas of specialty/work

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Postal code

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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