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-Premenstural 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)
Phone
+98 71 4352 7244
Email address
maryam.mahmoodi8874@gmail.com

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-ح 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 sssions 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

Street address
Imam Khomeini Town, Modarres Alley 4

City
Arsanjan

Province
Fars

Postal code
7376187999

Phone
+98 71 4352 7244

Email
maryam.mahmoodi8874@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Mirjali

Street address
Fars province, Arsanjan, Imam Khomeini town

City
yazd

Province
Yazd

Postal code
7376187999

Phone
+98 71 4352 7244

Email
maryam.mahmoodi8874@gmail.com

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

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
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Fars, Arsanjan city, Imam Khomeini town
City
Yazd
Province
Yazd
Postal code
7376187999
Phone
009843527244
Email
maryam.mahmoodi8874@gmail.com

Person responsible for scientific 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
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Fars, Arsanjan city, Imam Khomeini town
City
Yazd
Province
Yazd
Postal code
7376187999
Phone
009843527244
Email
maryam.mahmoodi8874@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Maryam Mahmoodi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Alley 4, Imam Khomeini Town, Arsanjan
City
Asanjan
Province
Fars
Postal code
7376187999
Phone
+98 71 4352 7244
Fax
Email
maryam.mahmoodi8874@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