Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

The Effect of Vitamin D and Vitamin E on Ameliorating Intensity and Duration of Dysmenorrhea in Iranian Women

Protocol summary

Study aim
The Effect of Vit D and Vit E Gelatin Capsuls on Severity and Duration of Dysmennorrhea in Women referred to Shahid Motahari gynecology clinics in Urmia

Design
A randomized, double-blind clinical trial with a control group and a parallel group design of 100 patients was conducted between 2016-2017

Settings and conduct
In this double-blinded randomized clinical trialIn 100 eligible women with dysmenorrhea who attended Kowsar gynecological clinic of Shahid Mottahari Hospital of Urmia University of Medical Sciences, during 2016-2017 categorized into four groups that received capsules containing a placebo (n = 25), 420 mg Vitamin D (n = 25), 400 mg Vitamin E (n = 25), and 420 mg Vitamin D + 400 mg Vitamin E (n = 25) every 24 hours for two consecutive months with starting at the beginning of the menstrual period

Participants/Inclusion and exclusion criteria
Patients were whom that has a history of primary dysmenorrhea over three menstrual cycles for at least one day per month they were studied inside . Any subjects with a history of chronic and systemic problems such as gynecological disease and significant medical history or active disease were excluded. Inclusion criteria were: being within the age group of 18-50 years; were no present history of gynecologic or psychological diseases, no urogenital disorders; no usage of herbal remedies, coagulation disorders or; regular menstrual cycles and no history of pelvic or abdominal surgery

Intervention groups
100 eligible women with dysmenorrhea categorized into four groups with 25 members. After that, the samples were determined randomly assigned to vitamin E group or Vitamin D group, vitamin E + Vitamin D group and placebo group (25 participants in each group).

Main outcome variables
Time of onset of pain, duration of pain, severity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160308026962N4**
Registration date: **2020-08-03, 1399/05/13**
Registration timing: **retrospective**

Last update: **2020-08-03, 1399/05/13**
Update count: **0**

Registration date
2020-08-03, 1399/05/13

Registrant information

Name
Tahereh Behroozi Lak

Name of organization / entity
Educational and Treatment Kowsar Center

Country
Iran (Islamic Republic of)

Phone
+98 44 3223 7077

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-01-05, 1394/10/15

Expected recruitment end date
2017-01-05, 1395/10/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Vitamin D and Vitamin E on Ameliorating Intensity and Duration of Dysmenorrhea in Iranian Women

Public title
Investigating the effect of vitamin D and vitamin E on Intensity and Duration of Dysmenorrhea

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Being within the age group of 18-50 years Were no present history of gynecologic or psychological diseases, no urogenital disorders No usage of herbal remedies No history of coagulation disordersand No history of iregular menstrual cycles No history of pelvic or abdominal surgery

Exclusion criteria:
Individuals with a history of specific illness Individuals with a history of forced drug use Individuals with a history of symptoms such as burning, itching, discharge, Individuals with a history of irregular periods

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
In this randomized clinical trial, samples will be randomly selected and randomly selected based on a table of random numbers into 4 equal groups of 25, including 3 experimental groups and a control group. In this study, assignment sequencing and preparation Supplemental and placebo packages in similar packages will be done by a person not involved in sampling and data collection. He did not know about the study groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is an RCT (randomized clinical trial) and will be performed on adouble-blind side . In this way, neither the subjects nor the person who will analyze the data will know which drug group and which treatment group received the treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciens

Street address
Urmia, Resalat Blvd, the end of Jahad St, Research ward, Setad, Urmia university of medical sciens

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2015-08-25, 1394/06/03

Ethics committee reference number
IR.UMSU.Rec.1394.63

Health conditions studied

1

Description of health condition studied
The Effect of Vitamin D and Vitamin E on Ameliorating Intensity and Duration of Dysmenorrhea

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain duration

Timepoint
Once before giving the desired treatments and placebo and once after a month and finally two months of continuous use of drugs and placebo

Method of measurement
Cox Menstrual Symptom Scale Questionnaires

2

Description
Severity of the pain

Timepoint
Once before giving the desired treatments and placebo and once after a month and finally two months of continuous use of drug and placebo

Method of measurement
Visual Analog Scale(VAS) Questionnaires

Secondary outcomes

1

Description
Time to start pain
Timepoint
Monthly
Method of measurement
Questionnaire before and after menstruation

2

Description
Menstrual status
Timepoint
Monthly
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group:Group receiving 50,000 mg of vitamin D gelatin capsule available from a pharmacy for three months to evaluate the duration and severity of dysmenorrhea
Category
Treatment - Drugs

2

Description
Intervention group:Group receiving vitamin E400 gelatin capsule, made by Dana Company in Iran for three months to evaluate the duration and severity of dysmenorrhea
Category
Treatment - Drugs

3

Description
Intervention group:Group receiving vitamin D and vitamin E gelatin capsules for three months to evaluate the duration and severity of dysmenorrhea
Category
Treatment - Drugs

4

Description
Control group: Group receiving placebo for three months to evaluate the duration and severity of dysmenorrhea
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Educational and Treatment Kowsar Center
Full name of responsible person
Tahereh Behroozi Lak
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Urmia, Resalat Blvd, the end of Jahad St. Urmia University of Medical Science
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
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Mohebbi_iraj@yahoo.co.uk
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Tahereh Behroozi Lak

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The data related to the participants' file can be accessed by correspondence by e-mail.

When the data will become available and for how long
Start the access period 6 months after publication of results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
The use of data for scientific research on topics related to the objectives of the study is unrestricted.

From where data/document is obtainable
To the person in charge of scientific response using their email

What processes are involved for a request to access data/document
Objectives and proposals should be sent by e-mail upon request by scientific authorities

Comments
In order to empower other researchers in the field of obstetrics and gynecology, we are ready to work with respected researchers.