Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Omega 3 fatty acids and vitamin E supplementation on symptoms of primary dysmenorrhea in resident students at Ahvaz Jundishapur University of Medical Sciences student accommodation: A randomized, single-blind, placebo-controlled clinical trial

Protocol summary

Summary

This is a clinical trial for evaluation of the effects of supplementation with vitamin E and omega- 3, on 100 students between 18 and 30 years, with primary dysmenorrhea in the girls dormitory of Ahvaz University of Medical Sciences. Inclusion criteria: having primary dysmenorrhea , single, living in dormitory and exclusion criteria include irregular menstrual cycles, abnormal discharge, itching and burning. Subjects were randomly divided into four groups (using table of random numbers) consist of recipients of supplemental vitamin E, omega 3 supplement, omega 3+ Vit E and placebo group (each group 25 cases). Vitamin E 200 units will be given orally for 5 days, 2 days before and 3 days after period to take a daily pill. Patients receive omega 3 daily 300 mg of Omega 3 (180 mg docosahexaenoic acid + 120 mg eicosapentaenoic acid) and the group receiving vitamin E and omega-3 daily (5 days), vitamin E 200 units +300 mg of omega-3 (180 docosahexaenoic acid acid mg +120 mg eicosapentaenoic acid). In this study supplement and placebo were similar in appearance and patients randomized to receive supplement and placebo and will be unaware of this issue. Duration of menstruation (days), the interval between periods (days), duration of pain at each time period (day and hour) and measurement of pain through questionnaires and standard tools (visual analogue scale) will be carried out.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102519669N1**
Registration date: **2014-12-17, 1393/09/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-12-17, 1393/09/26

Registrant information

Name

Hossein Khadem Haghighian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3375 2135

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-06-20, 1393/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Omega 3 fatty acids and vitamin E supplementation on symptoms of primary dysmenorrhea in resident students at Ahvaz Jundishapur University of Medical Sciences student accommodation: A randomized, single-blind, placebo-controlled clinical trial

Public title
Effect of Omega 3 fatty acids and vitamin E supplementation on symptoms of primary dysmenorrhea
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: People who have primary dysmenorrheal and use irregular NSAIDS and OCP.
Exclusion criteria: Patients with secondary dysmenorrhea (endometriosis, adenomyosis, leiomyoma, uterine anomaly, Endometrial Polyps, ovarian cyst).
Age
From **18 years** old to **30 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Factorial
Other design features
Qualified persons in each category will be selected with simple randomization and table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Science- Golestan Ave- Ahvaz
City
Ahvaz
Postal code
Approval date
2013-12-22, 1392/10/01
Ethics committee reference number
ajums.res.1392.358

Health conditions studied

1

Description of health condition studied
dysmenorrhoea
ICD-10 code
N94.4
ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
pain duration
Timepoint
at first and two months after intervention
Method of measurement
based on hours

Secondary outcomes

1

Description
Pain intensity
Timepoint
At first and two months after intervention
Method of measurement
Based on the VAS pain intensity

Intervention groups

1

Description
Intervention group III: vitamin E, 200 units + Omega 3, 300 mg(180 docosahexaenoic acid acid mg +120 mg eicosapentaenoic acid), Manufacturing in Zahravi pharmaceutical company, daily, two days before and three days of menstruation, two menstrual periods
Category
Treatment - Drugs

2

Description
Intervention group II: Omega 3, 300 mg(180 docosahexaenoic acid acid mg +120 mg eicosapentaenoic acid), Manufacturing in Zahravi pharmaceutical company, daily, two days before and three days of menstruation, two menstrual periods
Category
Treatment - Drugs

3

Description
Intervention group I:vitamin E, 200 units, Manufacturing in Zahravi pharmaceutical company, daily, two days before and three days of menstruation, two menstrual periods

Category
Treatment - Drugs

4

Description
Group IV: Placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dormitories of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Hossein Khadem Haghighian
Street address
Ahvaz Jundishapur University of Medical Science, Golestan Ave. Ahvaz
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr.Saki
Street address
Ahvaz Jundishapur University of Medical Science, Golestan Ave. Ahvaz
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences
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
Ahvaz Jundishapur University of Medical Science
Full name of responsible person
Dr. Sima Jafarirad
Position
Assistant Professor
Other areas of specialty/work
Street address
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Person responsible for scientific inquiries

Contact
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Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Science
Full name of responsible person
Hossein Khadem Haghighian
Position
Ph.D
Other areas of specialty/work
Street address
Ahvaz Jundishapur University of Medical Science, Golestan Ave. Ahvaz
City
Ahvaz

Postal code

Phone

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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