

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 +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

Email address

khadem.h@ajums.ac.ir

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 dysmenorrhea 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 addressAhvaz 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 addressAhvaz 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 sourceVice 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**Ahvaz Jundishapur University of Medical Science,
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Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Hossein Khadem Haghighian

Position

Ph.D

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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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