

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparing the effect of omega-3 with Vitamin E on the treatment of primary dysmenorrhea

Protocol summary

Summary

It is a double blind clinical trial to assess the efficacy of vitamin E and omega-3 in the treatment of primary dysmenorrhea. We will recruit 80 patients suffering from primary dysmenorrhea and allocate them into two matched groups randomly. 40 patients in group A are treated with 400mg of vitamin E and the other 40 patients (group B) are treated with omega-3. Intervention is continued for 2 month in both groups. The main outcomes are pain according to visual analogue scale (VAS) and duration of pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009044686N1**
Registration date: **2011-01-10, 1389/10/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-01-10, 1389/10/20

Registrant information

Name

Mehri Jamilian

Name of organization / entity

School of Medicine, Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1278 0660

Email address

mjamilian@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-01-20, 1389/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of omega-3 with Vitamin E on the treatment of primary dysmenorrhea

Public title

Comparing the effect of omega-3 with Vitamin E on the treatment 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 **15 years** old to **20 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Double 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 Arak University of Medical Sciences

Street address

School of Medicine, Arak University of Medical Sciences

City

Arak

Postal code

3816149369

Approval date

2011-02-28, 1389/12/09

Ethics committee reference number

4-72-88

Health conditions studied

1

Description of health condition studied

Dysmenorrhea

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

2

Description

pain intensity

Timepoint

at first and 2 months after intervention

Method of measurement

Based on the VAS pain intensity

Secondary outcomes

empty

Intervention groups

1

Description

Vitamin-E, 400 units, every other day for 2 months

Category

Treatment - Drugs

2

Description

Salmon fish oil, 500 mg (containing 180 mg of EPA and DHA 129 gram), daily for 2 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

One and two zones in high school education Arak

Full name of responsible person

Dr Mehri Jamilian (Gyn Specialist)

Street address

Taleghani Hospital

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Saeid Ashtiyani

Street address

Taleghani Hospital

City

Arak

Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Arak 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**

Arak University Of Medical Sciences

Full name of responsible person

Dr Mehri Jamilian

Position

Specialist Obstetrics & Gynecology /Faculty Member

Other areas of specialty/work**Street address**

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Full name of responsible person

Dr Mehri Jamilian

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University of Medical Sciences

Other areas of specialty/work**Street address**

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City

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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