Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 dysmenorrheal. 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 dysmenorrheal 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 intevention
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
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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