Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study on the effects of “Omega-3” and “Calcium” supplements to improve symptoms of primary dysmenorrhea in women referred to Gynecology clinic of Fatemieh hospital Hamedan, 2016

Protocol summary

Summary

The objective of this study is to compare the effects of two different supplements; omega 3 and calcium on primary dysmenorrhea. Main inclusion criteria are: age 18-35 and having mild to moderate primary dysmenorrhea and the main exclusion criteria are Changing Participant's mind for any reason and at any time and having any hypersensitivity to supplements in this study. In this randomized, double blind trial 80 women with primary dysmenorrhea are randomly divided into two interventional groups of 40. Each group is matched according to age, duration of cycles, length of menstruation, and BMI of candidates. Drugs are placed in the similar packets, encoding with A and B. Packets are given to the gynecologist and she will open the packets and read the code of each group. Group A is given Ibuprofen 400 mg plus 1000 mg Omega 3 and group B given Ibuprofen 400 mg plus 1000 mg Calcium. The objective drug and supplements are given everyday in the first cycle and from 8 days before till 2 days after initiation of menstruation for the second and third cycles. The intensity of pain and other symptoms like nausea, vomiting, mastalgia, headache or acne are recorded once before treatment and then after each menstruation period and measured by the visual analogue scale (VAS). At the end of the study recorded points are evaluated and statistically analyzed and superior treatment will be suggested.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042327539N1**
Registration date: **2016-06-04, 1395/03/15**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-06-04, 1395/03/15

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2016-05-15, 1395/02/26

Expected recruitment end date

2016-12-16, 1395/09/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effects of “Omega-3” and “Calcium” supplements to improve symptoms of primary dysmenorrhea in women referred to Gynecology clinic of Fatemieh hospital Hamedan, 2016

Public title

To compare the effects of “Omega-3” and “Calcium” supplements to improve primary dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age 18-35; Having mild to moderate primary dysmenorrhea; Not taking any medication to reduce mesturation pain except ibuprofen 400 mg not taking any omega3 and calcium supplement; Not having co-morbidity (secondary dysmenorrhea). Exclusion critria: Changing Participant's mind for any reason and at any time; Any hypersensitivity to the drugs in this study.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

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

Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Ayatollah kashani blv, Khaje rashid cross

City

Hamadan

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.UMSHA.REC.1395.93

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes

1

Description

Intensity of Dysmenorrhea

Timepoint

Pre and Post interventional phase (two menstrual cycle)

Method of measurement

VAS (visual analog scale)

Secondary outcomes

1

Description

Nausea; Vomiting; Bloating; Mastalgia; Acne; Headache

Timepoint

Each mensturation period

Method of measurement

Self-expressed Questionnaire

Intervention groups

1

Description

400 mg Ibuprofen plus 1000 mg Omega 3 daily in the first month and from 8 days before till 2 days after menstruation for the second and third cycles will be given

Category

Treatment - Drugs

2

Description

400 mg Ibuprofen plus 1000 mg Calcium daily in the first month and for the second and third cycles from 8 days before till 2 days after menstruation will be given

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology Clinic of Fatemieh Hospital

Full name of responsible person

D. Azami Fard

Street address

City

Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Amir Reza Fallahian
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Ilia apartment, Laleh alley, Shahid nazemi, pasdaran street
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Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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

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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