

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 2026

Oleoylethanolamide (OEA) supplementation effect on oxidative stress, prostaglandins, inflammatory factors and symptoms of primary dysmenorrhea in dormitory students in Qazvin University of Medical Sciences: A double-blind controlled clinical trial with placebo

Protocol summary

Study aim

The determination of antioxidant status, inflammatory factors and symptoms of primary dysmenorrhea in patients with primary dysmenorrhea

Design

In this study, 44 girls with primary dysmenorrhea who eligible for inclusion in the study and reside in dormitories of the Qazvin University of Medical Sciences are selected. Participants are randomly assigned to two intervention and control groups and each participant is assigned a code.

Settings and conduct

This study will be done by referring to the dormitories of the Qazvin University of Medical Sciences. The intervention and control group will receive 120 mg of Oleoylethanolamide or placebo daily for 2 months, respectively. Each person will complete questionnaires of consent, individual, physical activity, and 24-hour recall. Fasting blood samples were also collected at the beginning and end of the study in 10 ml from participants. In this study, participants will be randomly divided into two groups (22 persons) through the table of random numbers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having primary dysmenorrhea, having regular menstruation between 35-21 days, single, having a body mass index below 30 Exclusion criteria: Having secondary dysmenorrhea (endometriosis, adenomyosis, leiomyoma, uterine anomaly, Endometrial Polyps, ovarian cyst), intake of antioxidant supplement in the last six months, intake of fatty acids supplements in the last six months

Intervention groups

Intervention group: the group receiving Oleoylethanolamide (125 mg daily) Control group: placebo group

Main outcome variables

Oxidative stress indices, concentration of prostaglandins, inflammatory factors duration of bleeding, pain intensity of menstruation, duration of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141025019669N14**

Registration date: **2019-10-14, 1398/07/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-14, 1398/07/22**

Update count: **0**

Registration date

2019-10-14, 1398/07/22

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

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Oleoylethanolamide (OEA) supplementation effect on oxidative stress, prostaglandins, inflammatory factors and symptoms of primary dysmenorrhea in dormitory students in Qazvin University of Medical Sciences: A double-blind controlled clinical trial with placebo

Public title

Oleoylethanolamide (OEA) supplementation effect on symptoms of dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having primary dysmenorrhea Having regular menstruation between 35-21 days Single Having a body mass index below 30

Exclusion criteria:

Having secondary dysmenorrhea (endometriosis, adenomyosis, leiomyoma, uterine anomaly, Endometrial Polyps, ovarian cyst) Intake of antioxidant supplement in the last six months Intake of fatty acids supplements in the last six months

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

It will be done randomly using the lottery method. Each patient will receive a number or code, and then we will write the numbers on pieces of paper. We will then place the pieces of paper in a container and select the samples according to the sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

Supplements and placebo will be placed in similar containers and encode by someone except investigator, so patients and the investigator will be blinded to medicine and placebo groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University Of Medical Sciences

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2019-08-10, 1398/05/19

Ethics committee reference number

IR.QUMS.REC.1398.100

Health conditions studied**1****Description of health condition studied**

Primary dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes**1****Description**

Total antioxidant capacity

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

2**Description**

Malondialdehyde

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

3

Description

E2 prostaglandin

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

4

Description

F2α prostaglandin

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

5

Description

Inflammatory factors

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

6

Description

Duration of bleeding

Timepoint

Before the intervention and after the intervention

Method of measurement

According to a person's report by the questionnaire

7

Description

Pain duration

Timepoint

Before the intervention and after the intervention

Method of measurement

Duration of pain based on questionnaire

8

Description

Intensity of pain

Timepoint

Before the intervention and after the intervention

Method of measurement

Pain intensity according to the questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oleoylethanolamide, a capsule 120

mg per daily for two months, Manufacturer: Supplement Spot

Category

Treatment - Drugs

2

Description

Control group: A daily placebo capsule containing wheat flour for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Qazvin University of Medical Sciences

Full name of responsible person

Hossein Khadem Haghighian

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Peimani

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes
Title of funding source
Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Hossein Khadem Haghighian
Position
Faculty member
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data after people are unrecognizable
When the data will become available and for how long
After completing the study and analyzing the data
To whom data/document is available
All researchers
Under which criteria data/document could be used
There is no objection to the use of data provided the source of the resource.
From where data/document is obtainable

By contacting the email address of a person responsible
for general inquiries khademnut@yahoo.com
What processes are involved for a request to access

data/document
Six months after the study
Comments