Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 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

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Iran (Islamic Republic of)

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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
Street address
Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin
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Email
khademnut@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Peimani
Street address
Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin
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Postal code
34197-59811
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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

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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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