

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of alpha-Lipoic Acid supplementation on symptoms of primary dysmenorrhea in students residing in the dormitory of Qazvin University of Medical Sciences : A randomized, single-blind, placebo-controlled clinical trial

Protocol summary

Study aim

Determine of bleeding time, severity of menstrual pain, duration of pain

Design

In this study, 80 girls with primary dysmenorrhea who are eligible to enter the study are selected. Participants are randomly assigned to four intervention and control groups and each participant is assigned a code.

Settings and conduct

This study is a single-blind randomized clinical trial. Girls with primary dysmenorrhea living in student dormitory at Qazvin University of Medical Sciences entered the study. Then, 80 patients were randomly assigned to four intervention and control groups. In this study, the patient will be blinded to drugs and placebo.

Participants/Inclusion and exclusion criteria

Girls with primary dysmenorrhea

Intervention groups

First intervention group: Alfalipoic acid recipient group (600 mg daily); Second intervention group: Mefenamic acid group (250 mg daily); Third intervention group: Alfalipoic acid (600 mg daily) + Mefenamic acid (250 mg daily), control group: placebo group

Main outcome variables

Duration of bleeding, pain intensity of menstruation, duration of pain

General information

Reason for update

Acronym

ALA

IRCT registration information

IRCT registration number: **IRCT20141025019669N8**

Registration date: **2018-02-09, 1396/11/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-09, 1396/11/20**

Update count: **0**

Registration date

2018-02-09, 1396/11/20

Registrant information

Name

Hossein Khadem Haghghian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3375 2135

Email address

khadem.h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of alpha-Lipoic Acid supplementation on symptoms of primary dysmenorrhea in students residing in the dormitory of Qazvin University of Medical Sciences : A randomized, single-blind, placebo-controlled clinical trial

Public title

Alpha-Lipoic acid supplementation 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

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are randomly divided into two groups, intervention and control groups, using randomized distribution method. In this study, the patient is blinded to medicine and placebo

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

2018-01-22, 1396/11/02

Ethics committee reference number

IR.QUMS.REC.1396.387

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

Duration of bleeding

Timepoint

Before the intervention and after the intervention

Method of measurement

According to a person's report by the questionnaire

2

Description

Pain duration

Timepoint

Before the intervention and after the intervention

Method of measurement

Duration of pain based on hours

3

Description

Intensity of pain

Timepoint

Before the intervention and after the intervention

Method of measurement

Pain intensity according to the questionnaire

Secondary outcomes

1

Description

Pain duration

Timepoint

Before the intervention and after the intervention

Method of measurement

Duration of pain based on hours

Intervention groups

1

Description

Intervention group: Alfalipoic acid, 600 mg per daily

Category

Treatment - Drugs

2

Description

Intervention group: Mefenamic acid, 250 mg per day

Category

Treatment - Drugs

3

Description

Intervention group: Alfalipoic acid (600 mg) + Mefenamic acid (250 mg) daily

Category

Treatment - Drugs

4

Description

Control group: Plasebo

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

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

دکتر پیمانی

Street address

Qazvin University of Medical Science, Shahid Bahonar

Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

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

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

Person responsible for scientific 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
Street address
Qazvin University of Medical Science, Shahid Bahonar
Blvd, Qazvin
City
Qazvin
Province
Qazvin
Postal code
59811 -34197
Phone
+98 28 3333 6001
Email
khademnut@yahoo.com

Person responsible for updating data

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
Street address
Qazvin University of Medical Science, Shahid Bahonar
Blvd, Qazvin
City
Qazvin

Province
Qazvin
Postal code
34197-59811
Phone
+98 28 3333 6001
Email
khademnut@yahoo.com

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

Yes - There is 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

Data on primary and secondary outcomes will be published.

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

IRCT site

What processes are involved for a request to access data/document

Six months after the study

Comments