Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 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
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
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Sponsors / Funding sources

1

Sponsor
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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
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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
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