

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effect of flaxseed oil supplement on pain severity and systemic symptoms of primary dysmenorrhea in girl Students

#### Protocol summary

2017-05-26, 1396/03/05

##### Summary

object: Effect of flaxseed oil supplement on pain severity and systemic symptoms of primary dysmenorrhea in girl Students. In this 2 phase double blind clinical trial 60 female students would be randomly allocated to the supplement or placebo groups using random number tables. neither the participants nor administrator of the treatment know which capsules are being received. Inclusion criteria: single women between 18 and 25years; regular menstrual cycles; moderate or severe of primary dysmenorrhea was assessed with verbal multidimensional scoring system; body mass index range 18.5 to 24.9. Exclusion criteria: stressors in the past three months; History of surgery in abdomen or pelvic area. For the subjects in the intervention group, 1000 mg capsules of flaxseed oil was provided to consume in three times a day for 2 months. On the other hand, the control group received on placebo capsule that was similar the color and shape of flaxseed oil but included 1000 mg Paraffin, three times a day for 2 months. The questionnaires had given to participants until registering the pain intensity and systemic symptoms(sach as nausea, vomiting, diarrhea, headache, fatigue and backache) in the related forms after treatment during each menstruation period and to deliver to researcher after the end of period.

##### Registrant information

###### Name

Fatemeh Heidari

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 1373 8255

###### Email address

haidari-f@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Investigator

##### Expected recruitment start date

2017-03-05, 1395/12/15

##### Expected recruitment end date

2017-05-15, 1396/02/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017030810181N9**

Registration date: **2017-05-26, 1396/03/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

##### Scientific title

Effect of flaxseed oil supplement on pain severity and systemic symptoms of primary dysmenorrhea in girl Students

##### Public title

Effect of flaxseed oil on menstrual pain

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: single women between 18 and 25years; regular menstrual cycles; moderate or severe of

primary dysmenorrhea was assessed with verbal multidimensional scoring system; body mass index between 18.5 and 24.9 Exclusion criteria: stressors in the past three months; taking medications such as hormonal contraceptive; secondary dysmenorrhea; History of surgery in abdomen or pelvic area

#### Age

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

#### Gender

Female

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

In this double blind study neither the patients nor administering the treatment know which capsules are being received. The participants would be randomly allocated to the supplement or placebo groups using random number tables.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

##### Street address

Golestan Ave, Ahvaz Jundishapur University of Medical Science, Ahvaz

##### City

Ahvaz

##### Postal code

1579461357

#### Approval date

2017-01-07, 1395/10/18

#### Ethics committee reference number

ir.ajums.REC.1395.709

## Health conditions studied

### 1

#### Description of health condition studied

primary dysmenorrhea

#### ICD-10 code

N94.4

#### ICD-10 code description

primary dysmenorrhea

## Primary outcomes

### 1

#### Description

pain intensity

#### Timepoint

one cycle before and two cycles after intervention

#### Method of measurement

Based on the Visual Analogue Scale pain intensity

### 2

#### Description

systemic symptoms (nausea, vomiting, diarrhea, headache, fatigue, backache)

#### Timepoint

one cycle before and two cycles after intervention

#### Method of measurement

verbal multidimensional scoring system questionnaire

### 3

#### Description

pain duration

#### Timepoint

one cycle before and two cycles after intervention

#### Method of measurement

based on hours

## Secondary outcomes

### 1

#### Description

-

#### Timepoint

-

#### Method of measurement

-

## Intervention groups

### 1

#### Description

The flaxseed oil is receiving 1000 mg capsules of flaxseed oil three times a day for 2 months

#### Category

Treatment - Drugs

## 2

### Description

The placebo is receiving 1000 mg capsules of Paraffin three times a day for 2 months

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr. Haidari Fatemeh

**Street address**

Golestan Ave, Ahvaz Jundishapur University of Medical Science, Ahvaz

**City**

Ahvaz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr.Makhmalzadeh

**Street address**

Golestan Ave, Ahvaz Jundishapur University of Medical Science, Ahvaz

**City**

Ahvaz

**Grant name**

-

**Grant code / Reference number**

-

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Ahvaz 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

### Contact

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Narges Ahmadikhah

**Position**

Masters student of nutrition science

**Other areas of specialty/work****Street address**

Golestan Ave, Dept. of Nutrition, School of Paramedical, Ahvaz Jundishapur University of Medical Science, Ahvaz

**City**

Ahvaz

**Postal code**

1579461357

**Phone**

+98 61 3333 9092

**Fax**

+98 61 1373 8330

**Email**

Haidari58@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr. Haidari Fatemeh

**Position**

Associate Professor

**Other areas of specialty/work****Street address**

Golestan Ave. Dept. of Nutrition, School of Paramedical, Ahvaz Jundishapur University of Medical Science, Ahvaz

**City**

Ahvaz

**Postal code**

1579461357

**Phone**

+98 61 3333 9092

**Fax**

+98 61 1373 8330

**Email**

haidari-f@ajums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr. Fatemeh Heidari

**Position**

Associate Professor

**Other areas of specialty/work****Street address**

Golestan Ave, Dept. of Nutrition, School of  
Paramedical, Ahvaz Jundishapur University of Medical  
Science, Ahvaz

**City**

Ahvaz

**Postal code**

1579461357

**Phone**

+98 61 3333 9092

**Fax**

+98 61 1373 8330

**Email**

Haidari58@gmail.com

**Web page address****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*