

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Comparison of Flaxseed and Evening primrose oil with vitamin E on Cyclic Mastalgia in women

#### Protocol summary

##### Summary

The object of this study is to compare the effect of Flaxseed powder and Evening Primrose oil and Vitamin E capsules on cyclic mastalgia. This study 90 womens with cyclic mastalgia that referred to the Ghaeem(aj) Hospital or girls dormitories of Mashhad University of Medical Sciences. All the participants should complete inforemed consent.The participants will divided to 3 groups, each group daily 30 mg Flaxseed powder, or 1000 mg Evening Primrose oil twice a day or 400 IU Vitamin E daily.The severity and duration of breast pain will be evaluated ,before of treatment,first and second month of treatment with visual analog scale and daily check list

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015072123281N1**  
Registration date: **2015-12-02, 1394/09/11**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-12-02, 1394/09/11

##### Registrant information

##### Name

Elham Adib Moghadam

##### Name of organization / entity

Mashhad University of Medical Scinces

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3859 1511

##### Email address

adibme921@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University Of Medical Sciences

##### Expected recruitment start date

2015-10-23, 1394/08/01

##### Expected recruitment end date

2016-06-20, 1395/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparition of Flaxseed and Evening primrose oil with vitamin E on Cyclic Mastalgia in women

##### Public title

Comparition of Flaxseed and Evening Primrose oil with Vitamin E on Cyclic Mastalgia in women

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: cyclical mastalgia for 5 days or more in luteal phase for 2 menstrual cycle; mastalgia intensity of 4 or above based on visual analogue scale in the last cycle; aged 18 to 45 years; having literacy to read and write; living in Mashhad; Informed consent; body mass index between19-29; not taking any drugs for mastalgia in the last 3 month; regular menstrual cycles between 21 and 35 days; Lack of any cases of abnormality in clinical breast examination; not having the history of breast cancer or any kind of breast tumor in the person or first degree relatives like mother or sister; not being willing to get pregnant until the end of the study; not being in the lactation period; having no history of any kind of tumor and cancer in other organs; not being on a specific diet; having no history of any systemic and psychological

diseases; lack of a history of breast surgery and injection gel; lack of constipation exclusion criteria: pregnancy; taking any hormonal drugs like contraception pills; experiencing unexpected events during study; starting any kind of new lifestyle; having allergy or intolerance of supplements or side effects of drugs during study; disruption of eating flaxseed powder or capsules for frequent 3 days or constant 5 days; relinquishment to complete the study

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Mashhad University of Medical Science

**Street address**

Mashhad, Deputy of Research and Technology, After Hoveize Cinema, Daneshgah street, Mashhad University of Medical Science,

**City**

Mashhad

**Postal code**

91735951

**Approval date**

2015-11-09, 1394/08/18

**Ethics committee reference number**

IR.Mums.REC.1394.503

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

cyclic mastalgia

**ICD-10 code**

N64.4

**ICD-10 code description**

Mastodynia

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

severity of cyclic breast pain

**Timepoint**

at the beginning of the study- at the end of first cycle of intervention- at the end of the second cycle of intervention

**Method of measurement**

visual analog scale

**2****Description**

duration of the breast pain

**Timepoint**

at the beginning of the study- at the end of first cycle of intervention- at the end of the second cycle of intervention

**Method of measurement**

number of days in the related form

**Secondary outcomes**

empty

**Intervention groups****1****Description**

first intervention: flaxseed powder-15 g oral- twice daily(30 g)- for 2 menstrual cycle with water, juice, milk, soup, salad, yoghurt

**Category**

Treatment - Drugs

**2****Description**

intervention 2: 1000 mg evening primrose oil- oral capsul- twice daily for 2 menstrual cycle with 1 glass of water

**Category**

Treatment - Drugs

**3****Description**

intervention 3: vitamin E- oral capsul 400 IU- once a day for 2 menstrual cycle with one glass of water

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ghaem(AJ) Hospital

**Full name of responsible person**

Elham Adib Moghaddam

**Street address**

Mashhad, Shariati Square(Taghi Abad), Ahmad Abad Street, Ghaeem Educational, Research and Medical center

**City**

Mashhad

### 2

#### Recruitment center

**Name of recruitment center**

Girls dormitories of Mashhad University of Medical Sciences

**Full name of responsible person**

Elham adib Moghadam

**Street address**

Mashhad, Ebne Sina Street, Emam Reza Square,

**City**

Mashhad

### 3

#### Recruitment center

**Name of recruitment center**

Omolbanin Hospital

**Full name of responsible person**

Elham adib Moghadam

**Street address**

Mashhad, Behjat street, at the corner of Behjat 16

**City**

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Saieed Eslami

**Street address**

Mashhad, Deputy of Research and Technology, After Hoveyze Cinema, Daneshgah street, Mashhad University of Medical Science

**City**

Mashhad

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Farzane Jafar Nejad

**Position**

Master of Midwifery

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

Doctoor intersection, Ibn Sina Street

**City**

Mashhad

**Postal code**

0681697301

**Phone**

+98 51 3859 1511

**Fax****Email**

JaafarnejadF@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Farzane Jafar Nejad

**Position**

Master of Midwifery

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

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Elham adib Moghadam

**Position**

Graduate Student Midwives

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

Ibn Sina Street , Doctora intersection

**City**

Mashhad

**Postal code**

9137913199

**Phone**

00

**Fax****Email**

adibme921@mums.ac.ir

**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*