

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparition 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**

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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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Name of organization / entity

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Full name of responsible person

Elham adib Moghadam

Position

Graduate Student Midwives

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

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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