Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Uniersity 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 eventsduring studt; 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 capsuls tor 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 begining of the study- at the end of first cycle of intervention- at the end of the second sycle of intervention

Method of measurement
visual analog scale

2

Description
duration of the breast pain

Timepoint
at the begining of the study- at the end of first cycle of intervention- at the end of the second sycle 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 evevning 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
Doctoora 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
Doctoora 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 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