Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison effect of flaxseed dietary and supplementary of omega-3fatty acid on cyclical mastalgia intensity among referring women to hospitals of Shiraz university of medical sciences 2012-2013

Protocol summary

Summary

Mastalgia is one of the common complaints in women. Mild premenstrual breast pain that lasts less than 5 days is considered normal, but mastalgia with more intensity or duration can interfere with daily activities of life and sexual function and needs for treatment. Since the chemical drugs have serious side effects, herbal therapy and alternative medicine research is necessary. Due to antioxidant and hormonal potential effects of flaxseed, research team decided to examine the effects of flaxseed on mastalgia. Also due to antioxidant and anti-inflammatory beneficial effects of omega-3, the study will examine its effects on mastalgia, and the effectiveness will compare with flax seed effect. This study is a randomized clinical trial. The study population is women with moderate or severe mastalgia. 20-45 years old women without a history of breast and reproductive tract caners and other certain diseases will enter to this study and Allergic women to flaxseed or Omega-3 will be excluded. There are two experimental groups in this study. One group will receive 30 grams dietary flaxseed bread per day and the other group will receive one gram omega-3 per dayfor two menstrual cycles. Also a control group will receive wheat bread. After the end of every two menstrual cycles, a questionnaire will complete for each participants. The main variables that will asses are the severity and duration of mastalgia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010510327N3**
Registration date: **2013-07-01, 1392/04/10**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-07-01, 1392/04/10

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of flaxseed dietary and supplementary of omega-3fatty acid on cyclical mastalgia intensity among referring women to hospitals of Shiraz university of medical sciences 2012-2013

Public title

Comparison effect of flaxseed dietary and supplementary of omega-3fatty acid on cyclical mastalgia intensity among referring women to hospitals of Shiraz university of medical sciences 2012-2013

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with cyclic mastalgia; regular menstrual cycles between 24-35 days; 4 or more mastalgia pain with VAS scale; age between 20-40 years old; not breast feeding; not to get pregnant; BMI between 19 to 29; no premature menopause; no history of breast and endometrial cancer or ovarian cancer; non family history of breast cancer; no use of pharmaceutical and plant treatment during the study and no systemic disease or history of disease. Exclusion criteria: pregnancy; starts taking any medication during the study and sensitivity or intolerance to supplements.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic commity of shiraz university of medical sciences

Street address

ZAND AVENUE

City

Shiraz

Postal code

Approval date

2013-01-26, 1391/11/07

Ethics committee reference number

91/374702

Health conditions studied

1

Description of health condition studied

Mastalgia

ICD-10 code

N64.4

ICD-10 code description

Mastodynia

Primary outcomes

1

Description

Pain intensity

Timepoint

First, second and third months.

Method of measurement

visoual analogue scale

Secondary outcomes

1

Description

Pain duration

Timepoint

First, second and third months

Method of measurement

Interview

Intervention groups

1

Description

first interventional group: the group will receive Dietary flaxseed breads. This intervention continue for two menstrual cycles

Category

Treatment - Other

2

Description

second interventional group: the group will recive omega3 for 2 menstrual cycles

Category

Treatment - Drugs

3

Description

control group: this group will recived wheat bread for two menstrual cycles

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospitals of Shiraz University of Medical Sciences
Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Gholam Reza Hatam
Street address
Shiraz University of Medical Sciences, Zand Ave
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Fatemeh (PBUH) College of Nursing and Midwifery, Shiraz
Full name of responsible person
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Person responsible for updating data

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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