Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the effects of Evening Primrose and Vitamin B6 on the severity of mastalgia associated with fibrocystic breast changes.

Protocol summary

Summary

(1) Objective: Comparison of the effects of Evening Primrose and Vitamin B6 on the severity of mastalgia associated with fibrocystic breast changes. (2) Study design: The sampling will be random and triple blind. This study will be placebo-controlled and single center. The study population : All Iranian women with fibrocystic changes in breast Sample size: 96 (3) In this semi-experimental study will participate 96 subjects with mastalgia associated with fibrocystic changes. (4) Inclusion criteria : Iranian women aged 18 to 50 years before menopause; non-pregnant women; non-lactating women; women with mastalgi; rejection of cancer and other breast diseases based on clinical and laboratory evidence by specialist in surgery and breast diseases; not taking medications to reduce pain (eg Danazol, Tamoxifen, Bromocriptine) during the past three months. Exclusion criteria: Pregnancies; physical or mental illness during intervention; taking any herbal or chemical or hormonal drugs during the study; unwillingness to continue taking the medication as directed; No medicine use more than 5 days (5) Intervention: They are divided into three groups. Group 1: Evening primrose 2 capsules 1000 mg daily, group 2: Vitamin B6 2 capsules 50 mg daily, group 3: placebo 2 capsules daily, for three months (6) Primary outcome measure): severe of mastalgia

General information

Acronym

FCC - EPO

IRCT registration information

IRCT registration number: **IRCT2016062128574N1**
Registration date: **2016-07-02, 1395/04/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-07-02, 1395/04/12

Registrant information

Name

Rojin Tolouei

Name of organization / entity

Iran University of Medical Sciences, School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Evening Primrose and Vitamin B6 on the severity of mastalgia associated with fibrocystic breast changes.

Public title

Comparison of the effects of Evening Primrose and Vitamin B6 on the severity of mastalgia associated with fibrocystic breast changes.

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria : Iranian women aged 18 to 50 years before menopause; non-pregnant women; non-lactating women; women with mastalgi; rejection of cancer and other breast diseases based on clinical and laboratory evidence by specialist in surgery and breast diseases; not taking medications to reduce pain (eg Danazol, Tamoxifen, Bromocriptine) during the past three months. Exclusion criteria: pregnancies; physical or mental illness during intervention; taking any herbal or chemical or hormonal drugs during the study; unwillingness to continue taking the medication as directed; no medicine use more than 5 days
Age
From **18 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization: Sample allocation in the case and control group will be conducted randomly and using lottery through numbering 1, 2 and 3 on the cards. The samples will be asked to pick a card. By choosing a card, randomly the sample will be placed in one of the following groups: Group Evening Primrose (2 capsules 1000 mg daily), Vitamin B6 (2 capsules 50 mg daily) and placebo groups (2 capsules daily) Blinding:the medicine (Evening Primrose and Vitamin B-6) and placebo in the form of similar capsules will be produced by pharmacology advisor. Also putting capsules in the same containers and coding them will be performed by him. And at the end of the study and after analyzing the results, the capsule containers will be decoded. Thus, the samples are not aware of the contents of the medicine containers. As well as researchers and statistical analysts are not aware of the contents of the medicine containers and each groups What medications are taking. So, the study is a triple-blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
School of Nursing and Midwifery, Yasemi Rashid Street, Valiasr Street, Tehran
City
Tehran
Postal code
1996713883
Approval date
2016-06-12, 1395/03/23
Ethics committee reference number
IR. IUMS. REC 1395 - 9311373020

Health conditions studied

1

Description of health condition studied
Fibrocystic changes of breast
ICD-10 code
N60
ICD-10 code description
Benign mammary dysplasia

Primary outcomes

1

Description
The severity of mastalgia
Timepoint
Before the intervention, one month and two months and three months after intervention
Method of measurement
Visual analog scale questionnaires

Secondary outcomes

1

Description
Number of days with pain
Timepoint
Before the intervention, one month and two months and three months after intervention
Method of measurement
Daily record pain questionnaire

Intervention groups

1

Description
Intervention group: Evening Primrose group 2 capsules

1000 mg daily for 3 months, the Vitamins B 6 group, 2 capsules 50 mg daily for 3 months, Evening Primrose is made Barij, Vitamin B6 capsules made Shahid Beheshti University of Medical Science in the School of Pharmacy

Category

Placebo

2

Description

Control group: placebo 2 capsules daily for 3 months Placebo capsules, made School of Pharmacy Shahid, Beheshti University of Medical Sciences

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Breast Clinic of Milad hospital

Full name of responsible person

Doktor Maria Hashemian

Street address

Breast Clinic, Milad Hospital, next to Milad Tower, Hemmat Highway, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Morteza Naser Bakhat

Street address

Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran

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Tehran

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, Iran 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

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Full name of responsible person

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Position

Master student of midwifery

Other areas of specialty/work

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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