

# 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 mastalgia; 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)

###### Phone

+98 21 8888 2885

###### Email address

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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 mastalgia; 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

**City**

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**

Iran University of Medical Sciences, School of Nursing and Midwifery

**Full name of responsible person**

Rojin Tolouei

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Master student of midwifery

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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*