Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparing the analgesic effect of fluoxetine and vitamin E with vitamin E only in mastalgia due tofibrocystic breast disease

Protocol summary

Study aim
Evaluation the analgesic effect of fluoxetine in mastalgia due tofibrocystic breast disease

Design
In this study, 70 women with breast pain are devided by inclusion criteria in two groups.The intervention group: receive 600 units of vitamin E daily and 10 mg of fluoxetine for 8 weeks. Control group: receive 600 units of vitamin E and placebo daily for 8 weeks. After two months, the severity of the pain will be checked . All drugs are manufactured by Tehran Drug Company.

Settings and conduct
Phase 3 clinical trial study; Shahrekord Women's Clinic; Double blind that the researcher and the patient will have no aware of the contents of the capsules; Random allocation to two intervention and control groups

Participants/Inclusion and exclusion criteria
Women 20 to 50 years with fibrocystic breast disease-induced mastalgia; Women with mastalgia criterion equal to or greater than four on the VAS scale; Women whose pain lasts more than 5 days per month; The patient has no known history of brest disease or malignancy

Intervention groups
Intervention group: receive 600 units of vitamin E daily and 10 mg of fluoxetine for 8 weeks. Control group: receive 600 units of vitamin E and placebo daily for 8 weeks.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200205046381N1**
Registration date: **2020-02-28, 1398/12/09**
Registration timing: **prospective**
Last update: **2020-02-28, 1398/12/09**
Update count: **0**

Registration date
2020-02-28, 1398/12/09

Registrant information

Name
Maryam Pornafisi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3333 0065

Email address
nafisi@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the analgesic effect of fluoxetine and vitamin E with vitamin E only in mastalgia due tofibrocystic breast disease

Public title
Comparing the analgesic effect of fluoxetine and vitamin E with vitamin E only in breast pain due tofibrocystic breast disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women 20 to 50 years old with fibrocystic breast disease-induced mastalgia Women with mastalgia criterion equal to or greater than four on the VAS scale Women whose pain lasts more than 5 days per month The patient has no known history of brest disease or malignancy

Exclusion criteria:

Women with physical and mental illnesses such as polycystic ovary disease Obese female patients 30≥BMI Women who have been on hormone therapy for the past three months Women who use contraceptives

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation of the participants to the intervention 1 and 2 groups will be done using random allocation software. Then, envelopes prepare according to the number of participants in the study. It will be recorded number one on the first envelope, the second envelope number 2, and etc. In each envelope, the assignment of each individual is determined by the software. In this way, the specified envelope for each individual will be opened and the individual will be assigned to one of the intervention 1 and/or intervention 2 groups according to the option recorded in the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

A B C code is required for each group. All fluoxetine, vitamin E and placebo medications are put into the same capsules by the manufacturer and the investigator and particpant are not aware of the type of drug used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Vice Chancellor of Research and Technology, Shahrekord University of Medical Sciences,Kashani Blvd, Shahrekord,Iran

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718791

Approval date

2019-02-03, 1397/11/14

Ethics committee reference number

IR.SKUMS.REC.1397.298

Health conditions studied

1

Description of health condition studied

Mastalgia

ICD-10 code

N60.2

ICD-10 code description

Fibroadenosis of breast

Primary outcomes

1

Description

Pain

Timepoint

Baseline and two months after intervention

Method of measurement

VAS Questionaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive 600 units of vitamin E daily and 10 mg of fluoxetine per oral for 8 weeks. All drugs are manufactured by Tehran Drug Company

Category

Treatment - Drugs

2

Description

Control group: receive 600 units of vitamin E and

placebo daily per oral for 8 weeks. All drugs are manufactured by Tehran Drug Company

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar Hospital of Shahrekord

Full name of responsible person
Shabanian Sheida

Street address
Hajar Hospital of Shahrekord University of Medical Sciences, Parastar Avenue, Shahrekord, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Dr. Mehraban Sadeghi

Street address
Vice Chancellor of Research and Technology, Shahrekord University of Medical Sciences,Kashani Blvd, Shahrekord,Iran

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahre-kord University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Sheida Shabanian

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Total data in article format

When the data will become available and for how long
one years

To whom data/document is available
researchers

Under which criteria data/document could be used
publication

From where data/document is obtainable
journals

What processes are involved for a request to access data/document
publication of article

Comments