

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The comparison of effect of Flaxseed oil and vitamin E on severity of breast pain and nodularity in women with breast fibrocystic: A randomized double blind clinical trial

Protocol summary

Summary

Objectives: This study aims to determine the effect of Flaxseed oil on breast fibrocystic. **Design:** Double blind Randomized Controlled Trial **Setting and conduct:** This study will be conducted in Sari health center, Shahriar clinic. Eligible women will be selected with convenience sampling and will be randomly assigned into 2 groups of 50 subjects. A person from research team not involved in the recruitment and assigning participants will generate numbers of envelopes using a computerized program. Opaque sealed sequentially numbered envelopes will be used for allocation concealment. **Participants:** One hundred women aged 20 to 50 years old with breast fibrocystic **Interventions:** Intervention group will receive Flaxseed oil pearl (contain 350 mg alpha linoleic acid) twice a day and control group will receive vitamin E pearl 200 IU twice a day for two month. **Main outcome measures:** Duration and severity of breast pain will be evaluated by Cardiff chart and VAS before, first and second month after the intervention. **Secondary outcomes** include nodularity that will be respectively assessed by Lucknow-Cardiff scale before, first and second month after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612243014N18**
Registration date: **2017-10-15, 1396/07/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-15, 1396/07/23

Registrant information

Name

Shahram Ala

Name of organization / entity

Mazandaran University of Medical Sciences

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Phone

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sala@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2017-04-22, 1396/02/02

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effect of Flaxseed oil and vitamin E on severity of breast pain and nodularity in women with breast fibrocystic: A randomized double blind clinical trial

Public title

The comparison of effect of Flaxseed oil and vitamin E on severity of breast pain and nodularity in women with breast fibrocystic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged 20-50 years; willingness to participate in study; existence of lump or pain in breast examination; no willingness for pregnancy; having no malignancy
Exclusion criteria: sensitivity to Flaxseed oil; not willing to continue the study; breast-feeding women

Age

From **75 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Payambar azam university complex, 18 km Khazar abad road, Sari, Mazandaran, Iran

City

Sari

Postal code

Approval date

2017-04-19, 1396/01/30

Ethics committee reference number

IR.Mazums.Rec.96.2971

Health conditions studied

1

Description of health condition studied

Fibrosclerosis of breast

ICD-10 code

N60.3

ICD-10 code description

Cystic mastopathy with epithelial proliferation

Primary outcomes

1

Description

Breast pain severity

Timepoint

One month before intervention, first month after intervention, second month after intervention

Method of measurement

Cardiff chart, VAS

Secondary outcomes

1

Description

Breast nodularity

Timepoint

One month before, first and second month after intervention

Method of measurement

Lacknow-Cardiff scale

Intervention groups

1

Description

Control group will receive vitamin E pearl 200 IU twice a day for two month.

Category

Placebo

2

Description

Intervention group will receive Flaxseed oil pearl (contain 350 mg alpha linoleic acid) twice a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahriar clinic

Full name of responsible person

Street address

Qaran street, Sari, Mazandaran, Iran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Ahmadali Enayatifard

Street address

Vice chancellor for research, Moallem square, Sari,
Mazandaran, Iran

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

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Dr.Shahram Ala

Position

Professor of clinical pharmacy

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