Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Vitex agnus-castus and Flaxseed on duration and severity of breast pain in women with cyclical mastalgia: A randomised controlled trial

Protocol summary

Summary

Objectives: This study aims to determine the effect of Vitex agnus-castus and Flaxseed on cyclical mastalgia. Design: Triple blind Randomized Controlled Trial. Setting and conduct: This study will be conducted in Tabriz health centers. Eligible women will be selected with convenience sampling and will be randomly assigned into 3 groups of 53 subjects with block sizes of 3 and 6. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelops will be used for allocation concealment. Participants: 159 women aged 18 to 45 years old with cyclical breast pain. Interventions: One intervention group will receive Vitex agnus tablet (contain 3.2- 4.8 mg dry extract of vitex fruit, equal 0.42-0.58 mg Aucubin) twice a day plus flaxseed placebo and the other intervention group will receive flaxseed powder 25 grams in a cup of water per day plus Vitex agnus placebo for two menstrual cycles. The control group will receive placebo of flaxseed and Vitex agnus. Main outcome measures: Duration and severity of breast pain will be evaluated by Cardiff chart before, 1 and 2 months after the intervention. Secondary outcomes include perimenstrual symptoms, menstrual bleeding that will be respectively assessed by the Shortened premenstrual assessment form and Higham chart before, 1 and 2 months after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013070710324N14**
Registration date: **2013-12-09, 1392/09/18**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-12-09, 1392/09/18

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Vitex agnus-castus and Flaxseed on duration and severity of breast pain in women with cyclical mastalgia: A randomised controlled trial

Public title

The effect of Vitex agnus-castus and Flaxseed on duration and severity of breast pain in women with cyclical mastalgia.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Complaint of cyclical breast pain and tenderness; aged 18 to 45 years; Not currently taking hormonal contraception; having regular menstrual cycles (cycles 22 to 35 days) in the last 6 months; having a phone number for following; willingness to participate in study and having informed consent; being literate; cyclical breast pain and pain severity score above 7 according to chart Cardiff. Exclusion criteria: History of breast cancer; History of injury or wound in breast; using of medications that affect on breast pain (anti-depressants, digoxin, methyldopa, spironolactone, Chlorpropamide, danazol and tamoxifen); existence of lump or abnormalities in breast examination; existence of non cyclical breast pain or pain originates outside of the breast; history of asthma or allergies; taking dopamin agonist and antagonist (Levodopa, Amphetamine, Amphetamine, pergolide, Cabergoline, metoclopramide) in the last 6 months; history of breast cancer and other cancers in first-degree relatives; existence of known uterine myoma.

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **159**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

City
Tabriz

Postal code
66156-15733

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
9297

Health conditions studied

1

Description of health condition studied
Cyclical breast pain

ICD-10 code
N60-N64

ICD-10 code description
Disorders of breast

Primary outcomes

1

Description
Duration and severity of breast pain

Timepoint
Before intervention, 1 and 2 months after intervention

Method of measurement
Cardiff chart

Secondary outcomes

1

Description
Menstrual bleeding

Timepoint
Before intervention, 1 and 2 months afterintervention.

Method of measurement
Higham chart

2

Description
Perimenstrual symptoms

Timepoint
Before intervention, 1 and 2 months after intervention

Method of measurement
Shortened premenstrual assessment form

Intervention groups

1

Description
The control group will receive 25 gr placebo of flaxseed daily and placebo tablet of vitex agnus twice a day for

two menstrual cycles.

Category

Placebo

2

Description

The first intervention group will recieve tablet of vitex agnus made by Goldaru pharmaceutical company in Esfahan (contain 3.2- 4.8 mg dry extract of vitex fruit, equal 0.42-0.58 mg Aucubin) twice a day plus placebo of flaxseed daily for two menstrual cycles.

Category

Treatment - Drugs

3

Description

The second intervention group will recieve 25 grams of flaxseed powder in a cup of water daily plus placebo tablet of vitex agnus twice a day for two menstrual cycles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz health centers

Full name of responsible person

Ahmadpur Parivash

Street address

Nursing & Midwifery Faculty, South Shariati Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Shakouri Seyyed Kazem

Street address

Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

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, Tabriz 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

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Ahmadpur Parivash

Position

MSc student in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mirghafourvand

Position

PhD of reproductive health

Other areas of specialty/work

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Person responsible for updating data

Contact

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