Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Chamomile compaired to pelacebo on cyclic mastalgia in women

Protocol summary

Summary

The main purpose of study is checking the effect of Chamomile on pain of breast in women with cyclic Mastalgia. Subjects in study are women aged 18 to 45 years and must have cyclic mastalgia. Target sample size is 60 patients. Initial examination will be done by resident of Gynecology. If any suspicious mass be observed, mammogram or ultrasound must be done. All women more than 40 years should have mammogram or ultrasound during the past year. Women with benign or malignant disease؛ pregnant؛ lactating؛ using Steroid drugs؛ Danazol؛ Vit B6؛ Bromocriptine and Aspirin will be excluded from study. Visual Analogue Scale will be used and patients with pain for more than 5 days will be chosen as sample. Randomization will be done. Chamomile and pelacebo is used 5drops, 3 times a day for 2 cycle since the beginning to the end of menstrual cycle. At the end of study, questionnarei and examination will be done. Posible side effects include allergic reactions in sensitive people.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092525967N2**
Registration date: **2016-10-29, 1395/08/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-29, 1395/08/08

Registrant information

Name

Fahime Vafisani

Name of organization / entity

Ferdosi University

Country

Phone

Email address

fahimevafisani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Deputy for Research Mashhsad University of Medical Sciences

Expected recruitment start date

2015-05-23, 1394/03/02

Expected recruitment end date

2015-11-19, 1394/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Chamomile compaired to pelacebo on cyclic mastalgia in women

Public title

The effect of Chamomile on cyclic mastalgia in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged 18 to 45 years؛ pain of breast stsrted 2 weeks before menstruation and pain reduced with menstruation؛ approximate regular menstrual periods in recent 3 rounds Exclusion criteria: Underlying disease of uterin؛ breast and hormonal؛ pregnancy؛ lactating and menopause؛ using sex steroids؛ Danazol؛ oil of evening primrose؛ vitamin B6؛ NSAIDs؛ Bromocriptine؛ Selective Estrogen Receptor Inhibitors؛ regular use of Aspirin or other trearments to reduce pain of breast over the past two months.

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

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Depty for Research Mashhad University of Medical Sciences
Street address
Ghoreshi Building, In front of the 18th Daneshgah Avenue, Daneshgah Street
City
Mashhad
Postal code
11111-11111
Approval date
2013-10-19, 1392/07/27
Ethics committee reference number
IR.MUMS.REC.1392.152

Health conditions studied

1

Description of health condition studied
Mastodynia
ICD-10 code
N64.4
ICD-10 code description
Mastodynia

Primary outcomes

1

Description
Mastalgia
Timepoint
Before and after the intervention
Method of measurement
Using Visual Analogue Scale

Secondary outcomes

1

Description
Sensitivity to placebo or camomile
Timepoint
Before and after intervention
Method of measurement
Blood test

Intervention groups

1

Description
In main group, patients with moderate to severe pain of breast enter to the study. Chamomile were used 5 drops, 3 times a day for two cycle since the beginning to the end of the menstrual cycle. At the end of study, breasts were examined.
Category
Treatment - Drugs

2

Description
In intervention group, patients with moderate to severe pain of breast enter to the study. Pelacebo were used 5 drops, 3 times a day for two cycle since the beginning to the end of the menstrual cycle. At the end of study, breasts were examined.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Masumeh Ghazanfarpour
Street address
Ghaem Hospital, Taghi Abad Square, Ahmad Abad Street
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Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy for Research Mashhad University of Medical Sciences

Full name of responsible person
Dr.Mohsen Tafaghodi

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Ghoreshi Building, In front of the 18th Daneshgah Avenue, Daneshgah Street

City
Mashhad

Grant name

Grant code / Reference number

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

Title of funding source
Deputy for Research Mashhad 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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PhD Student of Pregnancy health

Other areas of specialty/work

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Full name of responsible person
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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