

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of Chamomile compared to placebo 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 placebo is used 5drops, 3 times a day for 2 cycle since the beginning to the end of menstrual cycle. At the end of study, questionnaire and examination will be done. Possible 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 Mashhad 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 compared to placebo 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 started 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 treatments 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

**City**

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

**Street address**

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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Masumeh Ghazanfarpour

**Position**

PhD Student of Pregnancy health

**Other areas of specialty/work****Street address**

College of Nursing and Midwifery, Doctora Crossroads

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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**Full name of responsible person**

Fahime Vafi Sani

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Masters Student of Nutrition

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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*