

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparative study of diclofenac and vitamin E, vitamin E alone and meloxicam and vitamin E in reducing pain in patients with mastalgia: randomized, double-blind clinical trial

#### Protocol summary

##### Study aim

A comparative study of diclofenac and vitamin E, vitamin E alone and meloxicam and vitamin E in reducing pain in patients with mastalgia: a double-blind randomized clinical trial

##### Design

Patients are randomly divided into three categories. The first group (vitamin E and diclofenac) should take one chewable 200 mg vitamin E tablet daily and two 25 mg diclofenac tablets. (68) In the second group (vitamin E alone), an oral chewable tablet of vitamin E at a dose of 200 mg daily, and the third group will take (vitamin E and meloxicam) an oral chewable tablet of vitamin E at a dose of 200 mg daily. Mg and meloxicam 15 mg daily for four months. Then every two weeks patients should be evaluated for pain intensity. After the doctor prescribes these drugs, another person who does not know the type of drugs prescribed, asks the patient about pain information by phone and records it in a questionnaire. The duration and severity of pain will be assessed by the VAS char.

##### Settings and conduct

This study is a clinical trial that after obtaining consent, patients referred to Khatam Al-Anbia and Honari clinic Comprehensive Cancer Center (PBUH) Peymaniyeh Hospital in Jahrom with mastalgia symptoms are randomly divided into three groups of 3/3. , The patient becomes blind ..

##### Participants/Inclusion and exclusion criteria

inclusion criteria: age over 18 years, the onset of pain at least 3 months ago, absence of pathological lesions such as cancer, cysts, etc.

##### Intervention groups

The first group will take (vitamin E and diclofenac) for 4 months the second group will take (vitamin E alone), for 4 months and the third group will take (vitamin E and meloxicam) for 4 months.

##### Main outcome variables

Patient pain after consumption Vitamin E and diclofenac  
Vitamin E alone Vitamin E and Moluxkiam

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210215050371N1**

Registration date: **2023-06-24, 1402/04/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-06-24, 1402/04/03**

Update count: **0**

##### Registration date

2023-06-24, 1402/04/03

##### Registrant information

##### Name

ahmadreza bazmjoo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5333 2414

##### Email address

ahmadreza1233@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-22, 1402/04/01

##### Expected recruitment end date

2024-12-30, 1403/10/10

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study of diclofenac and vitamin E, vitamin E alone and meloxicam and vitamin E in reducing pain in patients with mastalgia: randomized, double-blind clinical trial

**Public title**

Comparative study of diclofenac and vitamin E, vitamin E alone and meloxicam and vitamin E in reducing pain in patients with mastalgia: randomized, double-blind clinical trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

18 years old or above, pain started at least 3 months ago,

**Exclusion criteria:**

Pathologic mass like cyst, cancer etc... Failure to enter: lack of consent of the patient to participate in the study. End-stage diseases such as cancer, kidney failure, heart failure

**Age**

From **14 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyst
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples will be taken by simple random sampling. Then each member of the sample will be randomly assigned to one of the 4 subgroups: 1-diclofenac 2- diclofenac and vitamin E, 3-vitamin E alone 4-meloxicam and vitamin E with computer software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Outcome assessor and data analyzer and participant are blind (double blind). Outcome assessor and data analyzer and participant don't aware from grouping.

**Placebo**

Not used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of jahrom University of Medical Sciences

**Street address**

Ostad Motahari blvd , Jahrom city, Fars province, Iran

**City**

jahrom

**Province**

Fars

**Postal code****Approval date**

2021-01-10, 1399/10/21

**Ethics committee reference number**

IR.JUMS.REC.1399.107

**Health conditions studied****1****Description of health condition studied**

mastalgia

**ICD-10 code**

N64.4

**ICD-10 code description**

Mastodynia is the medical term describing the common symptom of breast pain

**Primary outcomes****1****Description**

Mastalgia

**Timepoint**

The intensity of the patient's pain is measured at the beginning of the study and then evaluated daily after the start of the treatment.

**Method of measurement**

Visual analog scale and breast pain chart

**Secondary outcomes**

empty

**Intervention groups****1****Description**

first Intervention group :Vitamin E and diclofenac) should take a simple oral chewable vitamin E tablet of 200 mg daily and two diclofenac 25 mg tablets daily.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: The second group (vitamin E alone), a simple and oral chewable tablet of vitamin E at a dose of 200 mg (based on previous research in this field) for 4 months

**Category**

Treatment - Drugs

**3**

**Description**

Intervention group: The third group (vitamin E and meloxicam) should be given a simple oral chewable tablet of this vitamin with a dose of 200 mg and meloxicam 15 mg daily for four months.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Jahrom EmamReza clinic

**Full name of responsible person**

Dr. Marzie Haghbin

**Street address**

Valiye Asr Ave, Jahrom city , Fars province

**City**

Jahrom

**Province**

Fars

**Postal code**

74198 86688

**Phone**

+98 71 5423 0011

**Email**

ahmadreza1233@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Dr Solhjoo

**Street address**

Motahari

**City**

Jahrom

**Province**

Fars

**Postal code**

7461419867

**Phone**

+98 991 043 8952

**Email**

ahmadreza1233@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Jahrom 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**

Jahrom University of Medical Sciences

**Full name of responsible person**

ahmadreza bazmjoo

**Position**

Med student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Biology

**Street address**

Daneshpoor Ave, Motahrai Ave ,Jahrom city, Fars province

**City**

Jahrom

**Province**

Fars

**Postal code**

7461419867

**Phone**

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**Email**

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**Person responsible for scientific inquiries**

**Contact**

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**Email**  
ahmadreza1233@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Jahrom University of Medical Sciences  
**Full name of responsible person**  
ahmadreza bazmjoo  
**Position**  
Med student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available