

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

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Province

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Postal code

74198 86688

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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

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7461419867

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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

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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