Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison effects of vitamin E and Diclofenac gel on breast pain in patients

Protocol summary

Summary

The aim of the study: Comparison effects of vitamin E and Diclofenac gel on breast pain in patients Study design: Randomized clinical trial, without blinding, placebo-controlled, single-center, Phase 4 trials Study population: All patients with breast pain that come to clinic Inclusion criteria: having breast pain for more than six month; Patients with substantial pain, its intensity by the physician (visual analog scale) is measured; Other diseases is rejected; infertility is rejected(woman 18_49 age) Exclusion criteria: existence underlying breast disease in examination or sonography if necessary or mammography if necessary; having systemic diseases affecting on breast pains; contrainndication of vitamin E use; contraindication of NSAIDs use includ asthma, Hives, cardiovascular disease, sever renal diease; last tree month of pregnancy and lactation; People who have done open-heart surgery; users of supplementry drugs, NSAID, sedatives, sexual hormonal drugs; addicts and people not trend to be treatment. Target sample size: 60 Intervention: Tab vitamin E 400 mg, Orally Intervention time: Daily, for two months Primary outcome: the pain Secondary outcomes: Digestive disorder, diarhea, Asthma, Hives, cardiovascular disorder, third month of pregnancy, lactation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061428464N1**
Registration date: **2016-07-24, 1395/05/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-07-24, 1395/05/03

Registrant information

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Recruitment status

Recruitment complete

Funding source

Sahebali manafi

Expected recruitment start date

2016-07-31, 1395/05/10

Expected recruitment end date

2017-08-01, 1396/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effects of vitamin E and Diclofenac gel on breast pain in patients

Public title

Comparson effects of vitamin E and Diclofenac gel on breast pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having breast pain for more than six month; Patients with substantial pain, its intensity by the physician (visual analog scale) is measured; Other diseases is rejected; infertility is rejected(woman 18_49

age) Exclusion criteria: existence underlying breast disease in examination or sonography if necessary or mammography if necessary; having systemic diseases affecting on breast pains; contrainndication of vitamin E use; contraindication of NSAIDs use includ asthma, Hives, cardiovascular disease, sever renal diease; last tree month of pregnancy and lactation; People who have done open-heart surgery; users of supplementry drugs, NSAID, sedatives, sexual hormonal drugs; addicts and people not trend to be treatment.

Age
From **18 years** old to **49 years** old

Gender
Female

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahroud University of Medical Sciences

Street address
Shahroud University of Medical Sciences, Shahrood, Semnan

City
Shahrood

Postal code

Approval date
2015-05-13, 1394/02/23

Ethics committee reference number
1394.28 ir.FHMU.REC.ir

Health conditions studied

1

Description of health condition studied
Breast pain

ICD-10 code
N64.4

ICD-10 code description
Mastodynia

Primary outcomes

1

Description
pain

Timepoint
The first day of intervention, 30 days after the intervention, 60 days after the intervention

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Digestive disorder, diarhea, Asthma, Hives, cardiovascular disorder, third month of pregnancy, lactation

Timepoint
The first day of intervention, 30 days after the intervention, 60 days after the intervention

Method of measurement
Questionnair

Intervention groups

1

Description
The case group: Tab vitamin E 400 mg, Daily, for two months, Orally

Category
Treatment - Drugs

2

Description
Control Group: Diclofenac Gel 1%, amount of 0/25 gr, Twice a day, for two month

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinic

Full name of responsible person
Dr.Seyed Fatemeh Amirkhalili

Street address
Mehr apartmant, 22 Bahman street, Shahrood, Semnan

City

Shahrood

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Republic Azad of Shahrrood University
Full name of responsible person
Dr.Sahebali Manafi
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Islamic Republic Azad of Shahrood University, Shahrood
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Shahrood
Grant name
_
Grant code / Reference number
_
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Republic Azad of Shahrrood University
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

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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