Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Comparative Study of Therapeutic effect of Vitamin B6 or E on Cyclic Mastalgia

Protocol summary

Summary

Cyclic mastalgia is a common condition in women seen in primary care practices. The clinical presentation is often described as premenstrual breast pain and tenderness at least five days and resolution of symptoms with menstruation. Nearly 70-80 percent of premenopausal women are affected by breast pain at some point in their life. The aim of this study is to evaluate the effectiveness of vitamin B6 and E for pain control in women with cyclic mastalgia. This double blind clinical trial will carry out in eighty women with premenstrual cyclic mastalgia in referents to medical and health centers in Hamadam city, Iran. Witten informed consent will obtain from all participants. The participants will randomly select to one of two months oral treatments groups: Vitamin E (200mg/day) or Vitamin B6 (40 mg/day). The severity of breast pain will measure by the visual analogue scale (VAS) and McGill pain questionnaire at enrollment and end of two months. Data will analyze by SPSS/16.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106266888N1**
Registration date: **2011-07-23, 1390/05/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-07-23, 1390/05/01

Registrant information

Name

Fatemeh Shobeiri

Name of organization / entity

Hamadan Universiy of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 6051

Email address

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Recruitment status

Recruitment complete

Funding source

Hamadan Univercity of Medical Sciences

Expected recruitment start date

2011-07-01, 1390/04/10

Expected recruitment end date

2013-02-01, 1391/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparative Study of Therapeutic effect of Vitamin B6 or E on Cyclic Mastalgia

Public title

Therapeutic effect of Vitamin B6 or E on Cyclic Mastalgia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Female; Age between 15-45; Not pregnant; Not breastfeeding; Lack of alleregy to drugs, Exclusion criteria: Women with age below 15 and above 45 years; Pregnancy; Lactation; Alleregy to drugs; Use of drugs (Hormonal;Danazol; Aspirin;Bromocriptine)

Age

From **15 years** old to **45 years** old

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Hamadan University of Medical Sciences
Street address
Fahmiheh Street, Hamadan University of Medical Sciences, Hamadan, Iran
City
Hamadan
Postal code
518/65178
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
d/p/16/35/9/784

Health conditions studied

1

Description of health condition studied
Cyclic Mastalgia
ICD-10 code
N64.4
ICD-10 code description
Cyclical breast pain can range intensity during menstruation

Primary outcomes

1

Description
cyclic mastalgia
Timepoint
Monthly
Method of measurement
According to Visual Analog Scale and Cradiff Breast Pain Chart

Secondary outcomes

1

Description
Nausea and Vomiting
Timepoint
Monthly
Method of measurement
According to person

Intervention groups

1

Description
Vitamin E, Oral tablet 200 mg, Dailiy along two months
Category
Treatment - Drugs

2

Description
Vitamin B6, Oral tablet 40 mg, Dailiy along two months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Medical and Health Center
Full name of responsible person
Nahid Mohammadi, M.Sc. of Health, Instructor
Street address
No. 11, Takgti Street, Shohada Medical and Health Center
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamadan University of Medical Sciences, Department of Research and Technology
Full name of responsible person
Fatemeh Asghari
Street address
No. 307, Fahmideh Street, Hamadan University of Medical sciences
City
Hamadan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamadan University of Medical Sciences, Department of Research and Technology
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
Hamadan University of Medical sciences
Full name of responsible person
Gita Sangestani
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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