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 Hamadan 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
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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 allergy to drugs, Exclusion criteria: Women with age below 15 and above 45 years; Pregnancy; Lactation; Allergy 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
None
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
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Country
Iran (Islamic Republic of)
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, Daily along two months
Category
Treatment - Drugs

2
Description
Vitamin B6, Oral tablet 40 mg, Daily 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
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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
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No. 307, Fahmideh Street, Hamadan University of Medical sciences
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Country
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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  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  empty
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