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. Written 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
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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

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 allerigy 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

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
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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Country
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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
Street address
  No. 307, Fahmideh Street, Hamadan University of Medical sciences
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  Hamadan
Country
  Iran (Islamic Republic of)
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

Contact
Name of organization / entity
Hamadan University of Medical sciences

Full name of responsible person
Gita Sangestani

Position
Instructor, M.Sc. of Midwifery

Other areas of specialty/work

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Associated Professor/ Ph.D. of Maternal and Health Child

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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