Evaluation of the effect of vitamin E on pelvic pain reduction in women suffering from primary dysmenorrhea

Protocol summary
Summary
The purpose of the present study is to evaluate the effect of vitamin E on the reduction of pelvic pain in women suffering primary dysmenorrhea. Methods: A double blind randomized clinical trial was performed on 140 women suffering primary dysmenorrhea. These women were randomly assigned into two groups and finally 94 women finished the study. In the case group (n= 42) vitamin E was prescribed as a dose of 400 IU daily starting 2 days before the beginning of menstruation and continuing for 3 days (total duration of 5 days), for two consecutive cycles. In the control group (n=52) a Placebo was prescribed which was completely similar to vitamin E pearls in shape, color, taste and smell. Pain severity was evaluated using Visual Analogue Scale (VAS) for one month before the study and during the 2 months of study.

General information
Acronym
IRCT registration information
IRCT registration number: IRCT138812222624N4
Registration date: 2010-05-03, 1389/02/13
Registration timing: retrospective

Last update:
Update count: 0
Registration date
2010-05-03, 1389/02/13

Registrant information
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Recruitment status
Recruitment complete
Funding source
Private

Expected recruitment start date
2008-01-01, 1386/10/11
Expected recruitment end date
2008-07-01, 1387/04/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of vitamin E on pelvic pain reduction in women suffering from primary dysmenorrhea

Public title
Effect of vitamin E on dysmenorrhea

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: single women aged between 18-25 whose dysmenorrhea started around menarche, without any increase during time, regular menstrual cycles and normal pelvic examination. Exclusion criteria: any surgical operation on pelvic and abdominal areas, history of genital infection or pelvic pain, use of other sedatives during the cycle, history of psychological problems or drug use, abnormal or heavy bleeding, smoking or alcohol consumption, digestive problems, prolonged stress in family or job, known pelvic or uterine anomaly, abnormal ultrasound of uterus and ovaries, possible
allergy to vitamin E.

**Age**
From 18 years old to 25 years old

**Gender**
Female

**Phase**
3

**Groups that have been masked**
No information

**Sample size**
Target sample size: 70

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Blinding (investigator’s opinion)
Double blinded

**Blinding description**
Placebo Used

**Assignment**
Parallel

**Other design features**
Secondary Ids
empty

**Ethics committees**

1

**Ethics committee**
Name of ethics committee
 Iran University of Medical Sciences
Street address
 Hemmat Highway, Chamran Cross.
City
 Tehran
Postal code

Approval date
2007-09-15, 1386/06/24

Ethics committee reference number
13233

**Health conditions studied**

1

**Description of health condition studied**
primary dysmenorrhea

**ICD-10 code**
N94.4

**ICD-10 code description**
Primary dysmenorrhoea

**Primary outcomes**

1

**Description**
pelvic pain reduction

**Timepoint**
2 months later

**Method of measurement**
VAS

**Secondary outcomes**
empty

**Intervention groups**

1

**Description**
vitamin E, 400 IU daily starting 2 days before the beginning of menstruation and continuing for 3 days

**Category**
Treatment - Drugs

2

**Description**
Placebo prescription

**Category**
Placebo

**Recruitment centers**

1

**Recruitment center**
Name of recruitment center
Iran University of Medical Sciences
Full name of responsible person
Dr. Maryam Kashanian
Street address
Akbarabadi Teaching Hospital
City
Tehran

**Sponsors / Funding sources**

1

**Sponsor**
Name of organization / entity
Investigator
Full name of responsible person
Dr. Maryam Kashanian
Street address
Akbarabadi Teaching Hospital
City
Tehran
Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

**Title of funding source**
Investigator

**Proportion provided by this source**
100

**Public or private sector**
empty
Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
eventy
Statistical Analysis Plan
eventy
Informed Consent Form
eventy
Clinical Study Report
eventy
Analytic Code
eventy
Data Dictionary
eventy