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

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

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 dysmenorrhea

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
Street address
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
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
Iran University of Medical Sciences
Full name of responsible person
Dr. Maryam Kashanian
Position
Associate Professor
Other areas of specialty/work
Street address
Akbarabadi Teaching Hospital
City
Tehran
Postal code
Phone
+98 21 5563 3244
Fax
Email
maryamkashanian@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Maryam Kashanian
Position
Associate Professor
Other areas of specialty/work
Street address
Akbarabadi Teaching Hospital
City
Tehran
Postal code
Phone
+98 21 5563 3244
Fax
Email
maryamkashanian@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Maryam Kashanian
Position
Associate Professor
Other areas of specialty/work
Street address
Akbarabadi Teaching Hospital
City
Tehran
Postal code
Phone
+98 21 5563 3244
Fax
Email
maryamkashanian@yahoo.com
Web page address

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