Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Name

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Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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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
Plecebo 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

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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