Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison effect of vitamin E and Fennel extract on severity primary Dysmenorrhea in girl students

Protocol summary

Summary

Introduction: primary dysmenorrhea is described as pelvic pain around the time menstrual bleeding in the absence of an identifiable pathologic lesion. it is a common gynecologic problem among women in reproductive age groups. Our objective was to compare the effect of vitamin E and Fennel extract on primary dysmenorrhea. A randomized single blind, Placebo-controlled trial carry out among 65 single female students who inclusion criteria are including regular menstruation periods; single girls, range age 18-26 years; moderate or severe degree of dysmenorrhea and exclusion criteria are including being affected by known diseases; signs of womb infections; precedent of phlogiston disease of pelvic, tumor; medicinal and herbal allergies; and appearance of stressful events (divorce and death of parents and relatives) have joined to the study group in recent 6 month and during the treatment period. Students divided into 3 groups randomly: Fennel extract, vitamin E and placebo. Groups used treatment four times a day from the onset of bleeding and continued through three days for two consecutive menstrual periods. Moreover, two questionnaires had given to them until registering the period (number of days pain) and intensity of pain (according VAS) in the related forms after treatment during each menstruation period and to deliver to researcher after the end of period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106046705N1**
Registration date: **2011-12-30, 1390/10/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-12-30, 1390/10/09

Registrant information

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Leila Moslemi
Name of organization / entity
Islamic Azad University Sari Branch
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and Technology, Islamic Azad University Sari Branch

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-11-22, 1390/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison effect of vitamin E and Fennel extract on severity primary Dysmenorrhea in girl students

Public title

Effect of herbal drugs on menstrual pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are including regular menstruation periods; single girls, range age 18-26 years; moderate or severe degree of dysmenorrhea and exclusion criteria are including being affected by known diseases; signs of womb infections; precedent of phlogiston disease of pelvic, tumor; medicinal and herbal allergies; and appearance of stressful events (divorce and death of parents and relatives) have joined to the study group in recent 6 month and during the treatment period.

Age
From **18 years** old to **26 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **65**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
قبلا در جایی ثبت نشده است

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Department of Research and Technology, Moalem square, Sari

City
Sari

Postal code

Approval date
2011-09-07, 1390/06/16

Ethics committee reference number
5-90

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
primary Dysmenorrhea

Timepoint
2 months

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Duration of Primary Dysmenorrhea

Timepoint
1 month before intervention and 2 months after intervention

Method of measurement
Number of days

Intervention groups

1

Description
100 unit vitamin E used treatment four times a day from the onset of bleeding and continued through three days for two consecutive menstrual periods.

Category
Treatment - Drugs

2

Description
CAP placebo four times a day from the onset of bleeding and continued through three days for two consecutive menstrual periods

Category
Placebo

3

Description
CAP Fenalgin 46 mg used treatment four times a day from the onset of bleeding and continued through three days for two consecutive menstrual periods.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of medical science Islamic Azad University Sari Branch

Full name of responsible person
Leila Moslemi, MSC Midwifery

Street address
Complex University, Faculty of medical science, Islamic Azad University Sari Branch, Firuzkande

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research and Technology, Islamic Azad University Sari Branch

Full name of responsible person
Dr Homayon Motameni

Street address
Firuzkande, Complex University of Islamic Azad Sari, Office building, the fifth floor, Vice chancellor for research

City
Sari

Grant name

Grant code / Reference number
-

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

Title of funding source
Vice chancellor for research and Technology, Islamic Azad University Sari Branch

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
Midwifery group, Faculty of medical science, Islamic Azad University Sari Branch

Full name of responsible person
Leila Moslemi

Position
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Person responsible for updating data

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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