

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 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

Name

Leila Moslemi

Name of organization / entity

Islamic Azad University Sari Branch

Country

Iran (Islamic Republic of)

Phone

+98 15 1213 3875

Email address

moslemi.leila@iausari.ac.ir

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

MSC Midwifery

Other areas of specialty/work**Street address**

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Web page address

-

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University Sari Branch

Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University Sari Branch

Full name of responsible person

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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