

# 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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**Postal code**

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**Phone**

+98 15 1213 3857

**Fax**

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**Email**

moslemi.leila@iausari.ac.ir

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

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**Web page address**

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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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**Web page address**  
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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*