Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Efficacy of oral fennel drop in treatment of primary dysmenorrhea

Protocol summary

Summary

Primary dysmenorrhea refers to the occurrence of painful menstrual cramps of uterine origin by a hypersecretion of endometrial prostaglandins and is a gynecological complaint. Common treatment for this problem is medical therapy such as mefenamic acid (NSAIDs drugs) or oral contraceptive pills, which both work by reducing myometrial activity. One of useful herbal agents to reducing potential dysmenorrhea is fennel. This randomized clinical trial (RCT) single central study was compared fennel drop with mefenamic acid for reducing pain of primary dysmenorrhea. Inclusion criteria: student; live in dormitory; not smoker; without any systemic disease. Exclusion criteria: intolerance to fennel drop .sixty College students with moderate dysmenorrhea were randomly selected and flowed up two cycles. Informed consent were completed by all participants.29 Of 30 students, continue the study in study group and 30 students reminded in control group. In first month no extra medications used, but in second month in study group was taken fennel drop (Fennelin Oral Drop,Each ml contatian 15.5 mg Antole,Barijessence.com,25 drop every 6 hour) and they can use mefenamic acid(cap mefenamic acid 250mg ,Darou Pakhsh pharmaceutical Mfg.Co.Tehran - Iran)if necessary. Intensity of pain was determined by visual analogue scale (VAS) . These cycles were assessed day by day. Bleeding in each cycle compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107096826N2**
Registration date: **2011-07-28, 1390/05/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-28, 1390/05/06

Registrant information

Name
Mahshid Bokaie
Name of organization / entity
Shahid Sadougi university of medical sciences,Yazd, Iran
Country
Iran (Islamic Republic of)
Phone
+98 35 1824 1751
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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences,Yazd, Iran

Expected recruitment start date

2010-08-17, 1389/05/26

Expected recruitment end date

2011-02-22, 1389/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of oral fennel drop in treatment of primary dysmenorrhea

Public title

Herbal drug and dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:student;live in dormitory;not smoker;without any systemic disease Exclusion

criteria:intolerance to fennel drop

Age
From **18 years** old to **25 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Sadoughi University of Medical sciences,Yazd, Iran

Street address
Bahonar sq-Shahid Sadoughi University of Medical sciences,Yazd, Iran

City
Yazd

Postal code

Approval date
2010-07-20, 1389/04/29

Ethics committee reference number
115799

Health conditions studied

1

Description of health condition studied
Dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
Pain reducing

Timepoint
Before mensturation,first day up fifth day of mensturation

Method of measurement
Visual analogos scale

Secondary outcomes

1

Description
Mesturation pattern

Timepoint
First day up fifth day of mensturation

Method of measurement
Pad count

Intervention groups

1

Description
cap mefenamic acid 250mg (Darou Pakhsh pharmaceutical Mfg.Co.Tehran - Iran) every 6 hour one cap PRN

Category
Treatment - Drugs

2

Description
Fennelin (Foeniculum vulgare) Oral Drop2%,Each ml contatian 15.5 mg Antole(Barijessence.com) active ingredient: Trans Antole, Phenshon, Methyl Chavcol, Estragon 25 drop every 6 hour every day until she needed

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Roghaye female stunent dormitory of Shahid Sadoughi University

Full name of responsible person

Street address

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical sciences,Yazd

Full name of responsible person

Fatemeh Ezodini Ardekani

Street address

Bahonar sq, Shahid Sadoughi University of Medical sciences,Yazd

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University of Medical sciences,Yazd

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

Shahid Sadougi University of Medical Sciences

Full name of responsible person

Mahshid Bokie

Position

MS

Other areas of specialty/work

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Position

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Other areas of specialty/work

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City

Yazd

Postal code

Phone

Fax

Email

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