

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of the effect of Fennel and Gelofen on the severity of primary Menstrual pain

Protocol summary

Summary

The study, of experimental study (double blind clinical trial) is to evaluate the effect of Fennel and Gelofen Capsule on Primary Dysmenorrhea on students residing in dormitories Islamic Azad University of Ardabil Branch in 1394 that among the 770 students living in dormitories 105 students with Dysmenorrhea volunteer for the study and are satisfied that the sampling will be selected from volunteers participating in the study, and of these, 72 patients with Primary Dysmenorrhea grade 2 and 3 that meet the specifications in the study are selected, then they will randomly divided into two groups: experience group (recipient of Fennel) and control group (receiving Gelofen) Data collection tools include questionnaire that will be 5 parts. Experimental group and control group, in the first 3 days per cycle periods, respectively will receive, Fennel Oil 3-5 drop into water or tea 3 times a day and Gelofen 400 milligram 4 Capsules per day (one capsule every 6 hours) for three consecutive cycles and will be followed-up and then after collecting the questionnaires, the data will be analyzed doing. The research hypothesis is as follows: There is no difference between the severity of the pain and associated symptoms during menstruation in students receiving Fennel and Gelofen.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060728313N1**

Registration date: **2016-08-12, 1395/05/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-12, 1395/05/22

Registrant information

Name

Roya Motavalli

Name of organization / entity

Islamic Azad University Of Ardabil Branch

Country

Iran (Islamic Republic of)

Phone

+98 45 3372 8024

Email address

m.motavalli@iauardabil.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University Of Ardabil Branch

Expected recruitment start date

2016-06-09, 1395/03/20

Expected recruitment end date

2016-09-10, 1395/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Fennel and Gelofen on the severity of primary Menstrual pain

Public title

The effect of Fennel on treatment Dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The incidence of primary dysmenorrhea grade 2 and 3 according to verbal multidimensional scoring criteria. Exclusion criteria: Use of birth control pills and herbal medicines; As well as painkillers and other relaxation techniques or

acupressure to relieve dysmenorrhea; Having of renal; hepatic; respiratory; and blood diseases; Having of sensitivity to NSAIDs and fennel.

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University Of Ardabil Branch

Street address

Basij Square, Ardabil, Iran

City

Ardabil

Postal code

5615731567

Approval date

2016-04-09, 1395/01/21

Ethics committee reference number

IR.IAU.ARDABIL.REC.1395.1

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

The severity of Menstrual pain

Timepoint

Three months after the beginning of interaction

Method of measurement

Verbal Multidimensional Scoring Criteria

Secondary outcomes

1

Description

Side Effects

Timepoint

Three months after the beginning of interaction

Method of measurement

Questionnaire

Intervention groups

1

Description

Medicine and registration form (for before and after the use of medicine) for the first cycle will be distributed and information on how to take the medicine is presented to everybody in Experimental Group. The Experimental Group will use Fennel Drop in three first day of Menstrual cycle, 3-5 drops in tea or water 3 times a day (every 8 hours) in 3 continuous series of Menstrual cycles. At the end of each cycle by fellow researchers collected clinical status and drug registration forms and will distributed new forms and medicine. The samples will be followed-up after three consecutive cycles. Verbal Multidimensional Scoring System to determine the severity of Menstrual pain is used to determine the presence or absence of symptoms associated with pain will be determined as well as through a Questionnaire.

Category

Treatment - Other

2

Description

Medicine and registration form (for before and after the use of medicine) for the first cycle will be distributed and information on how to take the medicine is presented to everybody in Control Group. The Control Group also use Gelofen Capsules at a dose of 400 milligram 4 times per day with meals or a glass of water in the first 3 days of the Menstrual cycle. At the end of each cycle by fellow researchers collected clinical status and drug registration forms and will distributed new forms and medicine. The samples will be followed-up after three consecutive cycles. Verbal Multidimensional Scoring System to determine the severity of Menstrual pain is used to determine the presence or absence of symptoms associated with pain will be determined as well as through a Questionnaire.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Student Dormitory Of Islamic Azad University Ardabil Branch

Full name of responsible person

Roya motavalli (Master of Midwifery, Faculty)

Street address

Hafez Street, Ardabil, Iran

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University Of Ardabil Branch

Full name of responsible person

Dr Mohamad Zaefizadeh (Research Assistant)

Street address

Basij square, Ardabil, Iran

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University Of Ardabil 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

Islamic Azad University Of Ardabil Branch

Full name of responsible person

Roya Motavalli

Position

Master of Midwifery, Faculty

Other areas of specialty/work

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Person responsible for scientific inquiries

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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