Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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 begining of interaction

Method of measurement
Verbal Multidimensional Scoring Criteria

Secondary outcomes

1

Description
Side Effects

Timepoint
Three months after the begining 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
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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
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Person responsible for scientific inquiries

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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