Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the Effect of Fenugreek Seed on Primary Dysmenorrhoea in the selected student Dormitories of Shahid Beheshty University of Medical Sciences

Protocol summary

Summary

This study was a double blind clinical trial, conducted on 101 students of Shahid Beheshty University of Medical Sciences. The study participants randomly assigned in terms of imagery severity dysmenorrhea in two groups of 50 and 51 persons. The persons were assessed in study groups regarding: age, menarche age, the early dysmenorrheal age, body mass index, graduate and parent's job, length; space and quantity of period in similar groups. Fenugreek seed's capsule content of 900 mg seed powder prescribed 3 times a day and 2- 3 capsules duration first three days of menstrual period and for persons in control group prescribed placebo (similar capsule with same recipe content starch) in two cycles. Severity of pain compared base on spectrum analog scale 0 to 10 centimeter (Mcgill scale) and systematic signs used verbal multidimensional scoring system said before study and duration 2 continuous cycles.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106196807N2**
Registration date: **2012-01-26, 1390/11/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-01-26, 1390/11/06

Registrant information

Name

Sedigheh Amir Ali Akbari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2272 9240

Email address

akbarisedd@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshty University of Medical Sciences

Expected recruitment start date

2011-08-06, 1390/05/15

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Effect of Fenugreek Seed on Primary Dysmenorrhoea in the selected student Dormitories of Shahid Beheshty University of Medical Sciences

Public title

Effect of Fenugreek Seed on Primary Dysmenorrhoea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: being unmarried; having moderate or severe dysmenorrhea according to Mc Gill pain rating scale; not known chronic diseases; having regular intervals of 21 to 35 days menstrual periods; no history of Myoma, Pelvic tumor, Andometriosis & PID; no symptoms such as burning, itching & abnormal discharge

during the study; no use of special drugs; no history of allergy to fenogreek or other plants and not taking herbal medicines during 3 months before intervention.
Exclusion criteria: allergy to fenugreek seed during intervention; incorrect taking the capsules; taking any other herbal medicine during intervention and taking less than 4 capsules daily.

Age
No age limit
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **101**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshty University of Medical Sciences
Street address
Tehran
City
Tehran
Postal code
Approval date
2011-07-24, 1390/05/02
Ethics committee reference number
1-7865-86-1-90

Health conditions studied

1

Description of health condition studied
Dysmenorea
ICD-10 code
N94.4
ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
Severity of pain
Timepoint
Two months before intervention and 2 months during intervention(3times during 3 days of menstration)
Method of measurement
Ruler of pain macgill; system of scali multiple verbal

2

Description
Severity of dysmenorrhea
Timepoint
Two months before intervention and 2 months during intervention
Method of measurement
Macgill pain scaling; multi verbalscaling

Secondary outcomes

1

Description
Dysmenorea
Timepoint
First three days of menstruation
Method of measurement
Mac gill scal

Intervention groups

1

Description
Control group: starch capsule, 500 mg , 3 times a day for 3 early periods day
Category
Placebo

2

Description
Intervention group: fenugreek seed capsule, 900mg 7 times a day for 3 early periods day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dormitory Yas Flower, Shahid Beheshty University of Medical Sciences
Full name of responsible person
Sima Younesi. MS of midwifery
Street address

Valiasr Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshty University of Medical Sciences

Full name of responsible person

Dr Masomeh Simbar

Street address

Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshty University of Medical Sciences

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 Beheshty University of Medical Sciences

Full name of responsible person

Sedigheh Amir Ali Akbari

Position

Faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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