

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

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

Protocol summary

Summary

This study was a double blind clinical trial, conducted on 101 students of Shahid Beheshti 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 Beheshti 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 Beheshti 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, Adometriosis & PID; no symptoms such as burning, itching & abnormal discharge

during the study; no use of special drugs; no history of allergy to fenugreek 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 Beheshti 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 verbal scaling

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 Beheshti University of Medical Sciences

Full name of responsible person

Sima Younesi. MS of midwifery

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Valiasr Street
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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
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Person responsible for scientific inquiries

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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