

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effect of capsule including Fenugreek seed versus placebo on severity and duration of pain in girls with primary dysmenorrhea: a single-blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of capsule including Fenugreek seed versus placebo on severity and duration of pain in girls with primary dysmenorrhea. Design: a single-blind randomized clinical trial. Setting and conduct: The eligible girl college students with primary dysmenorrhea who study at the Hamadan University of Medical Sciences during the study period will be enrolled into the trial. Inclusion criteria: single; age of 19 to 35 years; moderate to severe primary dysmenorrhea; regular periods of 21 to 35 days. Exclusion criteria: having chronic diseases; using any medications; sensitivity to Fenugreek; using any herbal drugs during the last 3 months; incomplete use of Fenugreek seed. Intervention group: two capsules including 900 mg Fenugreek seed every 8 hours from the first day of period or beginning of pain for 3 days in 2 consecutive months. Control group: two capsules of placebo every 8 hours from the first day of period or beginning of pain for 3 days in 2 consecutive months Primary outcome: (a) assessing the severity of pain every 8 hours during the period using McGill ruler pain; (b) assessing the duration of pain during the period on basis of day by taking history. Secondary outcome: Nothing. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: The participants will be unaware of the type of intervention. Therefore, the trial will be run as a single-blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608019014N107**

Registration date: **2016-08-04, 1395/05/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-04, 1395/05/14

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2006-04-21, 1385/02/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of capsule including Fenugreek seed versus placebo on severity and duration of pain in girls with primary dysmenorrhea: a single-blind randomized clinical trial

Public title

Effect of capsule including Fenugreek seed versus placebo on severity and duration of pain in girls with primary dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: single; age of 19 to 35 years; moderate to severe primary dysmenorrhea; regular periods of 21 to 35 days. Exclusion criteria: having chronic diseases; using any medications; sensitivity to Fenugreek; using any herbal drugs during the last 3 months; incomplete use of Fenugreek seed.

Age

From **19 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: The participants will be unaware of the type of intervention. Therefore, the trial will be run as a single-blind.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-04-09, 1395/01/21

Ethics committee reference number

IR.UMSHA.REC.1395.7

Health conditions studied**1****Description of health condition studied**

Primary dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes**1****Description**

assessing the severity of pain

Timepoint

every 8 hours during the period

Method of measurement

using McGill ruler pain

2**Description**

assessing the duration of pain

Timepoint

during the period

Method of measurement

on basis of day by taking history

Secondary outcomes**1****Description**

Nothing

Timepoint

Nothing

Method of measurement

Nothing

Intervention groups**1****Description**

two capsules of placebo every 8 hours from the first day of period or beginning of pain for 3 days in 2 consecutive months

Category

Treatment - Drugs

2**Description**

two capsules including 900 mg Fenugreek seed every 8 hours from the first day of period or beginning of pain for

3 days in 2 consecutive months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Nursing and Midwifery

Full name of responsible person

Reihaneh Ebrahimi

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan 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

School of Nursing and Midwifery

Full name of responsible person

Reihaneh Ebrahimi

Position

Midwifery Student

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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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