Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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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Hamadan

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

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

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