Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of hydroalcoholic extract of coriander seed on primary dysmenorrhea

Protocol summary

Study aim
Determining the effect of hydroalcoholic extract of coriander plant seeds on primary dysmenorrhoea

Design
Randomized Clinical trial, with parallel groups, triple-blind, phase 1 on 70 patients. Random Allocation Software was used for randomization.

Settings and conduct
70 students of Ferdowsi University girls dormitories are divided into two intervention and control groups. The study is triple blind and the participants, researchers and analysts are among the blinded groups.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: • Be single • Be in the age range of 18-30 years • Have regular menstrual cycles • Have moderate to severe dysmenorrhea • Do not have a history of pelvic and abdominal disease • Do not have a history of chronic diseases • Do not have a history of pain in the abdomen and back except during menstrual bleeding • Do not have a history of confirmed mental illnesses • Not having severe mental stress in the last 6 months • Not allergic to coriander • Informed consent Exclusion criteria: • Unwillingness to continue cooperation • Occurrence of a severe stressful event during the study period • Use of contraceptives • Irregular use of medicine or placebo • Getting married during the study period • Performing professional sports activities • Taking any type of supplement • Presence of benign breast or uterine cysts • They have had a history of prostate, breast cancer and ovarian cancer in their first degree relatives • Use of other herbs or drugs effective on dysmenorrhea

Intervention groups
Intervention group: 35 people from the sample size who are given medicine for five days in two menstrual cycles. Control group: 35 people from the sample size who are given placebo for five days in two menstrual cycles.

Main outcome variables
Intensity of primary dysmenorrhoea pain - duration of primary dysmenorrhoea pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230315057729N1**
Registration date: **2023-05-31, 1402/03/10**
Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**
Update count: **0**

Registration date
2023-05-31, 1402/03/10

Registrant information
Name
Zohre Shahri
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-06-10, 1402/03/20
Expected recruitment end date
2023-07-11, 1402/04/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
The effect of hydroalcoholic extract of coriander seed on primary dysmenorrhea

Public title
The effect of hydroalcoholic extract of coriander seed on primary dysmenorrhea

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Be single Be in the age range of 18-30 years Have regular menstrual cycles Have moderate to severe dysmenorrhea Do not have a history of pelvic and abdominal disease Do not have a history of chronic diseases Do not have a history of pain in the abdomen and back except during menstrual bleeding Do not have a history of confirmed mental illnesses Not having severe mental stress in the last 6 months Not allergic to coriander Informed consent to participate in the study

Exclusion criteria:
Unwillingness to continue cooperation The occurrence of a severe stressful event during the study period Taking contraceptives Irregular use of medicine or placebo in the amount of two consecutive doses Getting married during the study period Performing professional sports activities Taking any type of supplement and multivitamin Presence of benign breast or uterine cysts They have had a history of prostate cancer, breast cancer and ovarian cancer in their first degree relatives Use of other herbs or drugs effective on dysmenorrhea

Age
From **18 years** old to **30 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, permutation blocks method is used to assign people to the studied groups. Random allocation sequence of people will be done using Random Allocation Software and block size of four. The permutation block method is one of the random allocation methods in which each block is selected according to the number of studied groups. Sealed envelopes are used to hide the assignment. Based on the order of entry of the research units, the envelopes will be opened in order and the assigned group will be revealed.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This is a triple-blind study, in which participants, researchers and data analysts are among the blind groups of the study. In order to blind people, the drug and placebo are prepared in the form of capsules with completely similar packaging. There are codes on the packages that distinguish the drug from the placebo, and the researcher, research units and analysts are not aware of it.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Unit 11, Hafez Apartment, Farzangan Alley, Nasr Street

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743764

Approval date
2023-05-15, 1402/02/25

Ethics committee reference number
IR.MUMS.NURSE.REC.1402.018

Health conditions studied

1

Description of health condition studied
primary dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhea

Primary outcomes

1

Description
Intensity and duration of pain in early painful menstruation

Timepoint
Measuring the intensity and duration of painful menstruation at the end of menstrual bleeding during two consecutive cycles and simultaneously with the start

of the drug or placebo.

Method of measurement

Questionnaires made by the researcher. Visual Analogue Scale

Secondary outcomes

1

Description

The amount of menstrual bleeding - duration of menstrual bleeding - physical symptoms associated with menstruation

Timepoint

After the end of menstrual bleeding in two consecutive cycles and at the same time as giving medicine or placebo

Method of measurement

Questionnaires made by the researcher

Intervention groups

1

Description

Intervention group: 35 girls living in the dormitories of Ferdowsi University, who meet the inclusion criteria, were given oral capsules containing hydroalcoholic extract of coriander seeds with a dose of 500 mg for five days in two menstrual cycles. It is prepared and given by the pharmacist consultant professor, and during this time, the effect of the medicine on the intensity and duration of their menstrual pain is measured using designed questionnaires.

Category

Treatment - Drugs

2

Description

Control group: 35 girls living in the dormitories of Ferdowsi University who meet the inclusion criteria will be given an oral capsule containing a placebo (Avisel powder) for five days in two menstrual cycles.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ferdowsi University girls dormitories

Full name of responsible person

Zohre Shahri

Street address

Sarai Paradis 2, Danesh Blvd., in front of the Faculty of Literature and Humanities

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zohre Shahri

Position

Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available