

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of oral capsule of Apricot Kernel seed oil on primary dysmenorrhea

Protocol summary

Study aim

Determining the effect of oral capsule of apricot kernel oil on the intensity of early painful menstrual pain

Design

Clinical trial with control group, double blind, randomized, on 60 patients. For randomization, simple random allocation by coin flipping method was used.

Settings and conduct

Ferdowsi University of Mashhad dormitory. Medicine and placebo are given for 2 menstrual cycles. in each cycle for 5 days In this research, according to the order of entering the samples into the research, people with odd number of drug A and even number of drug B will be given (it should be mentioned that determining the drug with odd and even number is done by lottery).

Participants/Inclusion and exclusion criteria

Criteria for entering the study: Age 18 to 35 years, being single, onset of menstrual pain before the age of 20, experiencing pain and symptoms of moderate and severe dysmenorrhea, monthly bleeding and its regularity, low and moderate bleeding during menstruation, not suffering from chronic diseases, not having a positive history of inflammatory diseases Pelvis, myoma and pelvic tumors, not having a history of gynecological surgeries or abdominal surgery, not using oral contraceptives Exclusion criteria: Unwillingness to continue the research, not using the correct medicinal supplement and taking any medication effective on dysmenorrhea, duration of dysmenorrhea longer than the normal time defined for primary dysmenorrhea.

Intervention groups

Students with primary dysmenorrhea are divided into 2 intervention and control groups. The intervention group received apricot kernel oil capsules and the control group received placebo capsules.

Main outcome variables

Pain intensity; duration of pain; accompanying physical symptoms; Bleeding rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230615058488N1**

Registration date: **2023-06-22, 1402/04/01**

Registration timing: **prospective**

Last update: **2023-06-22, 1402/04/01**

Update count: **0**

Registration date

2023-06-22, 1402/04/01

Registrant information

Name

Shamim Eskandari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of oral capsule of Apricot Kernel seed oil on primary dysmenorrhea	
Public title	Investigating the effect of apricot kernel oil on primary dysmenorrhea
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Age 18 to 35 years, being single, the onset of menstrual pain before the age of 20 (primary dysmenorrhea usually affects girls under 20 years old), experiencing pain and symptoms of moderate and severe dysmenorrhea, monthly bleeding and its regularity with intervals of 21 to 35 days, Low and moderate bleeding during menstruation (absence of clot discharge), not suffering from chronic diseases (diabetes, hyperthyroidism and hypothyroidism, chronic liver or kidney disease and diagnosed depression, not having a history of gastric or duodenal ulcers), not having a positive history of pelvic inflammatory diseases , myoma and pelvic tumors, not having a history of gynecological surgery or abdominal surgery (including any type of open surgery or laparotomy and laparoscopy in the pelvic area such as cysts, masses, adhesions), not using oral contraceptives, benzodiazepines, barbiturates, narcotics , some antidepressants such as fluoxetine and anticoagulants, not consuming alcohol, not having symptoms such as burning, itching and abnormal discharge in the genital area, not having a history of allergies to medicinal plants, not having experienced major stressors such as the separation of parents or the death of a first-degree relative in In the last six months, not being forced to consume a special diet and professional and heavy sports, not smoking, not having plans to transfer, move, party in another university or graduate during the study period. Exclusion criteria: In the event of: unwillingness to continue the research, failure to use the correct medicinal supplement and use of any medication effective on dysmenorrhea, the duration of dysmenorrhea is longer than the normal time defined for primary dysmenorrhea.
Age	From 18 years old to 35 years old
Gender	Female
Phase	3
Groups that have been masked	- Participant - Investigator
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Simple random allocation by coin flipping method According to the order of entering the samples into the research, people with odd numbers will be given
	medicine A and people with even numbers will be given medicine B. For example, the first person entered into the study receives drug number 1 and drug A, and the second person receives drug number 2 and drug B. One of the two drugs A and B is apricot kernel oil and the other is a capsule similar to placebo. It should be mentioned that the determination of the medicine is done by lottery.
Blinding (investigator's opinion)	Double blinded
Blinding description	In this research, sufficient explanations about the study and that the people will be divided into two groups are given to the subjects. The first person entered into the study is given drug A and the second person is given drug B. It should be noted that the people involved in the research, the project manager, the main researcher, the statistical consultant professor do not know which of the two drugs A and B are apricot kernel oil and which one is the placebo. Only the pharmacist consultant is aware of this matter.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	<u>1</u> Ethics committee Name of ethics committee Ethics committee of Mashhad University of Medical Sciences Street address Unit 14, No 5, Arian building, Majidiyeh 33/8 street City Mashhad Province Razavi Khorasan Postal code 9186366964 Approval date 2023-05-30, 1402/03/09 Ethics committee reference number IR.MUMS.NURSE.REC.1402.035
Health conditions studied	<u>1</u> Description of health condition studied Primary dysmenorrhea ICD-10 code N94.4 ICD-10 code description Primary dysmenorrhoea

Primary outcomes

1

Description

Dysmenorrhoea pain intensity

Timepoint

The beginning of the study, the end of the first menstrual cycle and the end of the second menstrual cycle

Method of measurement

Visual Analogue Scale

2

Description

Frequency of physical symptoms of dysmenorrhea

Timepoint

The beginning of the study, the end of the first menstrual cycle and the end of the second menstrual cycle

Method of measurement

Standard verbal multidimensional scoring system

3

Description

Duration of primary dysmenorrhoea pain

Timepoint

The beginning of the study, the end of the first menstrual cycle and the end of the second menstrual cycle

Method of measurement

Cox Menstrual Scale

Secondary outcomes

1

Description

The amount of menstrual bleeding

Timepoint

Before starting the intervention, the end of the first menstrual cycle and the end of the second menstrual cycle

Method of measurement

Higham chart

Intervention groups

1

Description

Intervention group: Students with primary dysmenorrhea who take 900 mg apricot kernel oil oral soft gelatin capsule for 2 menstrual cycles and each cycle for 5 days (2 days before menstruation to 3 days after menstruation).

Category

Treatment - Drugs

2

Description

Control group: Students with primary dysmenorrhea who

take the placebo soft gelatin capsule, which is the same shape and size as the apricot kernel oil capsule, for 2 menstrual cycles and each cycle for 5 days (2 days before the onset of menstruation to 3 days after the onset of menstruation) they consume

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ferdowsi University of Mashhad dormitory

Full name of responsible person

Shamim Eskandari

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Ferdowsi University of Mashhad, Azadi Square

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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
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available