Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of oral tablet of Black cohosh on the menstrual symptoms and dysmenorrhea among female students: a randomized controlled trial

Protocol summary

Study aim
The purpose of this study is to determine the effect of oral black cohosh tablets on dysmenorrhea and menstrual symptoms in student girls

Design
randomized clinical trial with control group Three-way blind and phase 2 The sample size was calculated to be 50 people (25 people in each group).

Settings and conduct
This study will be conducted on students of Khoy University of Medical Science. They will be contacted using the list of students and a simple random method, and those who meet the basic conditions will be invited to attend the meeting hall of the faculty. Find out the objectives of the study and the method is explained. Eligible people will be assigned to two groups using a random method. The drug and placebo will be placed inside numbered opaque glasses to hide the allocation. Both the participants, the researcher, and the analyst will be blinded. For the control group, a placebo similar to the main drug will be prepared by the pharmaceutical company, and the list of drugs will be at the disposal of the non-involved person. Medicines will be taken for 2 cycles and in each cycle 5 pills before and 2 pills after the start of menstruation and one pill daily.

Participants/Inclusion and exclusion criteria
Inclusion criteria: regular menstruation for 21-35 days Having primary dysmenorrhoea (with VAS score ≥ 4) Age 18-30 years not married Having complaints of menstrual symptoms Exclusion criteria: Use of other herbal medicines and painkillers Having any acute or chronic disease History of any female disease such as abnormal pelvic anatomy, lack of ovulation, or abnormal pattern of uterine bleeding. First semester students

Intervention groups
Black cohosh medicine for the intervention group and placebo for the control group

Main outcome variables
dysmenorrhea, Menstrual symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240510061726N1**
Registration date: **2024-07-29, 1403/05/08**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-29, 1403/05/08**
Update count: **0**

Registration date
2024-07-29, 1403/05/08

Registrant information

Name
nasrin zamiri-miandoab

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3633 2112

Email address
nasriinzamiri@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-14, 1403/02/25

Expected recruitment end date
2024-11-21, 1403/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of oral tablet of Black cohosh on the menstrual symptoms and dysmenorrhea among female students: a randomized controlled trial

Public title

The effect of oral tablet of Black cohosh on the menstrual symptoms and dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Regular menstruation 21-35 days Age 18-30 years insensitivity to black cohosh and other herbal medicines containing phytoestrogens (soybeans, flax seeds, lentils, mung beans, etc.) According to the person's statement Not taking any medication to treat dysmenorrhea at the same time as research Having primary dysmenorrhea (with VAS score ≥ 4) Not having liver problems according to the person's own statement not married Complaining of menstrual symptoms (cramps, headache, abdominal pain, mood disorders, etc.)

Exclusion criteria:

First semester students Use of other herbal medicines and painkillers. The occurrence of a stressful event (such as the death of a first-degree family member and the diagnosis of an incurable or incurable disease for a family member during the last three months) Abuse of tobacco and alcohol Having any acute or chronic disease (such as epilepsy, cardiovascular, digestive, liver, blood, endocrine) History of any female disease such as abnormal pelvic anatomy, lack of ovulation, or abnormal pattern of uterine bleeding Surgery in the last three months Insensitivity to black cohosh and other herbal medicines containing phytoestrogens (soybeans, flax seeds, lentils, mung beans, etc.)according to the person's statement. Taking antidepressants (such as serotonin and noradrenaline reuptake inhibitors, antihistamines, barbiturates, narcotics, diazepam, amphetamines, and cocaine)

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: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The list of students is taken and they are selected by a simple random method and they are contacted. Qualified people are randomly allocated into two black cohosh groups using a random block size of four and six blocks and with a ratio of 1:1. and a placebo will be placed. The pills are placed in opaque bottles numbered consecutively and will be delivered to the participants in the order they enter the study. The researcher and the participants will not know the type of drug. It should be noted that the placebo will be completely similar to the original drug in terms of shape, color, and other appearance characteristics and will be manufactured by the pharmaceutical company.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, there will be three blinded sides.Participants, the researcher and the analyst will be blind. The type of original drug and placebo will be the same in terms of shape, color, smell and size, and none of the participants will be aware of the type of drug used. In the same way, the researcher and the analyst will not know the type of drug and the list of drugs will be at the disposal of the person not involved in the study.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of khoy University of Medical Sciences

Street address

khoy, Valiasr Blvd, khoy University of Medical Sciences

City

خوی

Province

West Azarbaijan

Postal code

5816753464

Approval date

2024-05-01, 1403/02/12

Ethics committee reference number

IR.KHOY.REC.1403.004

Health conditions studied

1

Description of health condition studied

Dysmenorrhea and premenstrual symptoms

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes

1

Description
menstrual symptoms
Timepoint
The beginning of the study and the end of the study
Method of measurement
Menstrual symptoms intensity scale SSS

2

Description
primary dysmenorrhea
Timepoint
The beginning of the study and the end of the study
Method of measurement
visual pain scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the intervention group, black cohosh herbal medicine with the medicinal name of Simi Fogel, which Gol Daru Company manufactures, will be used. This medicine is in the form of coated tablets that contain 6.5 mg of dry extract of black cohosh root. This medicine will be taken 7 tablets monthly (5 tablets on the day before menstruation and 2 tablets during menstruation) by female students for 2 months. The pharmacist approves this treatment protocol of the team, and in previous similar articles, the same dose has been used on menopause
Category
Treatment - Drugs

2

Description
Control group: For the control group, the placebo drug will be made exactly the same as the original drug by Isfahan Gol Daru Company
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khoy Faculty of Medical Sciences
Full name of responsible person
Nasrin Zamiri-Miandoab
Street address
Khoy, Valiasr Blvd, Khoy Faculty of Medical Sciences,
City
khoy
Province
West Azarbaijan
Postal code
5816753464
Phone
+98 44 3625 5777
Email
nasriinzamiri@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoy University of medical science
Full name of responsible person
Nasrin Zamiri_miandoab
Street address
khoy, valiasr blvd,
City
khoy
Province
West Azarbaijan
Postal code
5816753464
Phone
+98 44 3625 5777
Email
nasriinzamiri@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoy University of medical science
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
khoy university of medical science
Full name of responsible person
nasrin zamiri-miandoab
Position
Instructor of Midwifery
Latest degree

Master

Other areas of specialty/work
Midwifery

Street address
khoy, Valiasr blvd,

City
khoy

Province
West Azarbaijan

Postal code
5816753464

Phone
+98 44 3625 5777

Email
nasriinzamiri@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Khoy University of medical science

Full name of responsible person
Nasrin zamiri-miandoab

Position
Instructor of midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Khoy, Valiasr Blvd

City
Khoy

Province
West Azarbaijan

Postal code
5816753464

Phone
0098443625777

Email
nasriinzamiri@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Khoy University of medical science

Full name of responsible person
Nasrin zamiri-miandoab

Position
Instructor of midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Khoy, valiasr Blvd

City
Khoy

Province
West Azarbaijan

Postal code
5816753464

Phone
+98 914 381 0756

Email
nasriinzamiri@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Parts of the data, such as information related to the main outcome, will be report after de-identifying people

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
researchers and students

Under which criteria data/document could be used
Study data can only be used by mentioning the source

From where data/document is obtainable
The scientific response of the study to the treatment of Nasrin Zamiri Miandoab with the email address nasriinzamiri@gmail.com

What processes are involved for a request to access data/document
The applicant can receive the data by sending an email to the corresponding author

Comments