Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

the effect of Hypericum perforatum Plant oil on the severity pain of primary dysmenorrhea

Protocol summary

Study aim
Determining the effect of hofarikun vegetable oil on the severity of primary dysmenorrhea
Design
A clinical trial with a control group, with parallel groups, three blind strains, randomized based on the table of random numbers and phase 3 will be conducted on 100 girls with primary dysmenorrhea.
Settings and conduct
This study will be conducted in the dormitories affiliated with Jundishapur University of Medical Sciences, Ahvaz. First, the patients will be followed up for 2 consecutive cycles, in terms of determining grade 2 or 3 dysmenorrhea. Then, 100 students were randomly divided into two intervention and control groups after being diagnosed with grade 2 or 3 dysmenorrhea.
Participants/Inclusion and exclusion criteria
1- Has grade 2 and 3 primary dysmenorrhea based on multidimensional speech criteria 2- Full consent to participate in the study 3- Regular menstrual cycles with intervals of 21 to 35 days 4- Menstrual bleeding without clots (light and moderate bleeding) 5- The onset and duration of primary dysmenorrhea from a few hours before menstruation to the second day of bleeding 6- History of allergy to herbal medicines 7- Absence of stressful factors in the last two months, special dietary needs 8- No history of pelvic inflammatory disease, myoma and pelvic tumors
Intervention groups
For the intervention group, Hofarikun oil produced by Zardband company and of high quality is purchased. For the control group, paraffin oil will be used. How to complete the checklist and how to take medicines will be taught by the researcher to the patients in both intervention and control groups. In such a way that the patient applies 5 drops of the oil from 5 days before menstruation to 2 days after the start of menstruation and for 2 consecutive cycles and every day 5 drops locally and for 15 minutes in the upper part of the pubis, in a circular manner.
Main outcome variables
intensity of pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231017059753N2**
Registration date: **2024-01-18, 1402/10/28**
Registration timing: **prospective**

Last update: **2024-01-18, 1402/10/28**
Update count: **0**
Registration date
2024-01-18, 1402/10/28

Registrant information
Name
leila bozorgian
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 74 3323 0240
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-02-19, 1402/11/30
Expected recruitment end date
2024-04-18, 1403/01/30
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of Hypericum perforatum Plant oil on the severity pain of primary dysmenorrhea

Public title

the effect of Hypericum perforatum Plant oil on the severity pain of primary dysmenorrhea

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from grade 2 and 3 primary dysmenorrhea according to verbal multidimensional criteria Female students aged 17-30 years Absence of medical illness (diabetes, blood pressure, epilepsy, any kind of heart disease, rheumatism, and neurological diseases...) Has grade 2 and 3 primary dysmenorrhea based on multidimensional speech criteria Full consent to participate in the studyf Regular menstrual cycles with intervals of 21 to 35 days6- Menstrual bleeding without clots (light and moderate bleeding) Menstrual bleeding without clots (light and moderate bleeding) The onset and duration of primary dysmenorrhea from a few hours before menstruation to the second day of bleeding - Not using anticoagulants, narcotics, benzodiazepines Not using contraceptive pills, painkillers and other herbal medicines as well as relaxation methods or acupressure to relieve primary dysmenorrhea. History of allergy to herbal medicines Absence of stressful factors in the last two months, special dietary needs - No history of pelvic inflammatory disease, myoma and pelvic tumors

Exclusion criteria:

Continuous use of nutritional supplements and vitamins

Age

From **17 years** old to **30 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be in the form of random block sampling based on the purpose and according to the study entry criteria. We consider the block size to be 5. Therefore, based on the sample size, we will have 20 blocks. When sampling starts, the first block will be randomly assigned one of the codes A or B. Based on the received code of the first block, the second code will be sent to the second block, the first code will be sent to the third block, the second code will be sent to the fourth block, and so on until the end of the 20th block.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Hypericum perforatum oil and paraffin oil (placebo) will be matched by the pharmacist in terms of appearance, color, size, smell, and code (A and B). The researcher, the service provider, the data analyst, and the patient are unaware of the type of drug used, and only the pharmacist will be aware of this coding.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz University of Medical Sciences

Street address

Ahvaz Golestan, North Esfand St

City

Ahvaz

Province

Khouzestan

Postal code

15794- 61357

Approval date

2023-12-15, 1402/09/24

Ethics committee reference number

IR.AJUMS.REC.1402.487

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

N73.8

ICD-10 code description

Other specified female pelvic inflammatory diseases

Primary outcomes

1

Description

intensity of pain

Timepoint

Subjects will fill the questionnaires half an hour after oil massage during the second day of menstruation in both consecutive cycles.

Method of measurement

McGill pain questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: The drug used for the intervention group is hofaricon oil. This drug was manufactured by Danesh Banyan Zardband company with high quality and was purchased from this company. The patient will be instructed to apply 5 drops of the oil from 5 days before menstruation to 2 days after the onset of menstruation and for 2 consecutive cycles and every day 5 drops locally for 15 minutes on the upper part of the pubis. The face should be massaged circularly from the center point to the size of the palm.

Category

Treatment - Drugs

2

Description

Control group: Control group: The drug used for the control group is paraffin oil. The patient will be instructed to apply 5 drops of the oil from 5 days before menstruation to 2 days after the onset of menstruation and for 2 consecutive cycles and every day 5 drops locally for 15 minutes on the upper part of the pubis. The face should be massaged circularly from the center point to the size of the palm.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Girls' dormitories affiliated to Ahvaz University of Medical Sciences

Full name of responsible person

leila bozorgian

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Ahvaz, Golestan, North Esfand St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehrnoosh Zakir Kish

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

leila bozorgian

Position

PhD student in midwifery

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