

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

comparision of the effect of Fennelin and diclofenac on primary dysmenorrhea

Protocol summary

Study aim

Determining and comparing the effect of Fennelin and diclofenac, on primary dysmenorrhea

Design

A clinical trial with two intervention groups, Double blind study, Randomized by block method, on 100 patients.

Settings and conduct

The study will be conducted on women with dysmenorrhea who refer to specialized gynecology and obstetrics clinics and medical centers. If they have moderate to severe primary dysmenorrhea, they will be included in the study. They will be randomly divided into two intervention groups using the randomized block method. It will be performed in a double-blind manner, so that the patients and the researcher will not know the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: moderate and severe dysmenorrhea. Age between 15-30 years. Regular menstruation

Intervention groups

Intervention group 1: Fennelin 30 mg Pearl manufactured by Barij Essential Oil Pharmaceutical Company is taken three times a day for 4 days, one tablet each time and in two menstrual cycles. Intervention group 2: Diclofenac 100 mg tablet manufactured by Hakim Pharmaceutical Company, three times a day for 4 days. And every time one number is consumed in two menstrual periods

Main outcome variables

severity of dysmenorrhea, Nausea, vomiting, back pain with dysmenorrhea

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20220512054829N2**

Registration date: **2022-10-28, 1401/08/06**

Registration timing: **retrospective**

Last update: **2022-10-28, 1401/08/06**

Update count: **0**

Registration date

2022-10-28, 1401/08/06

Registrant information

Name

Hossein Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5554 0111

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-30, 1401/05/08

Expected recruitment end date

2022-08-19, 1401/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparision of the effect of Fennelin and diclofenac on primary dysmenorrhea

Public title

effect of Fennelin on primary dysmenorrhoea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Regular menstruation Moderate and severe dysmenorrhea Age between 15-30

Exclusion criteria:

People with underlying diseases User of other drugs genital diseases

Age

From **15 years** old to **30 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Randomization is done with the block method (Permuted block randomization) so that first All blocks of four that include two codes A and B (6 blocks) are prepared and numbers from 1 to 6 are assigned to each of them. Then, using the table of random numbers, each number from 1 to 6 that is selected, the block corresponding to each code will be written(25 blocks). Based on this, a sequence of codes A and B is prepared for 100 codes (proportionate to the number of samples). Then, each of the letters A and B is randomly assigned to one of the fennelin and diclofenac groups. The same code is recorded on each drug and will remain with the formulation department until the end of the study. At the end of the study, the code of the drugs in the form of A and B will be provided to the statistical analyst for analysis.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs in both groups are packaged In vials of one shape and one size in the formulation section of Barij Essential Oil Pharmaceutical Company, then coded based on codes previously prepared using a random number table.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Faculty of Medicine & Faculty of Dentistry- Kashan University of Medical Science

Street address

Kashan University of Medical Sciences ,Pezeshk street ,Ghotb ravandi BLVD

City

Kashan

Province

Isfahan

Postal code

8715985131

Approval date

2022-07-03, 1401/04/12

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1401.068

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

Moderate to severe dysmenorrhoea according to Andresh and Milsom questionnaire

Timepoint

Examination of the severity of dysmenorrhea at the beginning of the study before the intervention and on the 1st, 2nd, 3rd and 4th day of menstruation after the intervention.

Method of measurement

Andres and Milsom questionnaire

Secondary outcomes

1

Description

Nausea with dysmenorrhea

Timepoint

At the beginning of drug use and days 1, 2, 3, and 4 of dysmenorrhea in two consecutive menstrual periods

Method of measurement

Andrash and Milsom questionnaire

2

Description

Vomiting with dysmenorrhea

Timepoint

At the beginning of drug use and days 1, 2, 3, and 4 of dysmenorrhea in two consecutive menstrual periods

Method of measurement

Andrash and Milsom questionnaire

3**Description**

Back pain with dysmenorrhea

Timepoint

At the beginning of drug use and days 1, 2, 3, and 4 of dysmenorrhea in two consecutive menstrual periods

Method of measurement

Andrash and Milsom questionnaire

Intervention groups**1****Description**

Intervention group 1: People take one 30 mg pearl fennelin three times a day after meals with the onset of dysmenorrhea. Each milliliter of this substance contains less than 11.4 mg of anthole as an active ingredient. Phenylin has similar packaging as Diclofenac with the name "Stapin" is designed by Barij Essential Oil Pharmaceutical Company .The drug is used for two menstrual periods and for four days in each period

Category

Treatment - Drugs

2**Description**

Intervention group 2: People take one 100 mg diclofenac tablet three times a day with the onset of dysmenorrhea after meals. Diclofenac has the same packaging as fennelin with the name "Stopain" designed by Hakim Pharmaceutical Company .The drug is used for two menstrual periods and for four days in each period.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti Clinic, Kashan

Full name of responsible person

Zahra Vahedpour

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kashan 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

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Hosseini Akbari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biostatistics
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

It is possible to share some of the data

When the data will become available and for how long

The access period begins one year after the publication of the article

To whom data/document is available

All faculty members of medical universities

Under which criteria data/document could be used

If they want to do more accurate statistical analysis on the data or use newer diagnostic methods to measure the outcome of the intervention

From where data/document is obtainable

Call and email

What processes are involved for a request to access data/document

By calling or e-mailing the person in charge and signing a memorandum of cooperation regarding the service he is going to provide and the benefits that will reach the parties.

Comments