Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

comparsion 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 between15-30 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

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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
comparsion 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

Isfehan

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
Street address
Shahid Beheshti Hospital,Qutb Rawandi BLVD
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholamali Hamidi
Street address
Kashan University of Medical Sciences, Qutb ravandi BLVD
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hamidi_gh@yahoo.com
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
Hossein Akbari
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work

Biostatistics

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Person responsible for updating data

Contact

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Latest degree
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Other areas of specialty/work
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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