Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Preparation of phytosome containing Foeniculum vulgare essential oil and its evaluation in reducing the pain intensity of primary dysmenorrhoea patients

Protocol summary

Study aim
Determining the effect of phytosome formulation containing fennel essential oil in reducing pain intensity in patients with primary dysmenorrhea

Design
A clinical trial with a control group, with parallel groups, three blind strains, randomized by stratified random assignment method, phase 2 on 144 patients.

Settings and conduct
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Participants/Inclusion and exclusion criteria
Inclusion criteria: women with regular menstrual cycle suffering from primary dysmenorrhoea whose body mass index is also determined (less than or greater than 25). Exclusion criteria: use of birth control pills, painkillers, and other herbal medicines, as well as relaxation methods or acupressure to relieve primary dysmenorrhea; suffering from known kidney diseases; hepatic; respiratory and blood; Having an allergy to non-steroidal anti-inflammatory drugs and fennel, a history of severe or moderate anemia

Intervention groups
4 groups receiving 4 doses of prepared phytosome (3 doses containing antole in low, medium, high doses and 1 dose without anethole (placebo)) and mefenamic acid.

Main outcome variables
Pain level is measured by two methods of interview and VAS questionnaire (0-10) at the beginning and end of each cycle during 3 consecutive cycles.

General information

Reason for update

Acronym
AFP

IRCT registration information
IRCT registration number: **IRCT20100420003760N6**
Registration date: **2023-03-29, 1402/01/09**
Registration timing: **prospective**

Last update: **2023-03-29, 1402/01/09**
Update count: **0**

Registration date
2023-03-29, 1402/01/09

Registrant information

Name
Marzieh Rashidipour

Name of organization / entity
Lorestan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2023-06-24, 1402/04/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Preparation of phytosome containing Foeniculum vulgare essential oil and its evaluation in reducing the pain intensity of primary dysmenorrhoea patients

Public title
Investigating the analgesic effect of Foeniculum vulgare essential oil phytosome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with regular menstrual cycles with primary dysmenorrhea whose body mass index is also determined (less than or greater than 25).
Exclusion criteria:
Use of birth control pills Use of pain relievers Using pain relief methods such as acupressure Suffering from certain diseases Having an allergy to non-steroidal anti-inflammatory drugs and fennel
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of patients into four groups and also using stratified random allocation. In this way, classes are made based on age group (below 30 years and greater than or equal to 30 years), primary dysmenorrhea severity (moderate or severe), body mass index status (less than 25 and greater than or equal to 25) are constructed (12 classes in total).. Within each class, random permutation blocks are used to assign samples to the required groups. To create random sequences, letters A, B , C or D(corresponding to the experimental group) will be used as follows. ABCD: 0-3 ABDC: 4-7 ACBD: 8-11 ACDB:12-15 . . DABC DBAC DCAB DCBA: 92-95 Then a corner of the table of random numbers is selected and two-digit numbers are read from top to bottom, and finally, according to the read number, a random sequence of letters A to D is registered in the desired floor. Finally, a random sequence of letters A to D (corresponding to the 4 experimental groups) will be created in each class of all existing classes, and the samples will be assigned to 4 groups based on this random sequence.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study will be triple blind, which means that the pain intensity assessor, the patient and the data analyst are not aware of the type of treatment assigned to the patient. In addition, the decipherer is not a member of the research team and the edible capsules in all groups are completely identical in appearance. Data registration in the statistical software and data analysis is done by the statistical consultant without mentioning the names of the groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Lorestan University of Medical Sciences
Street address
No 20, Anooshirvan Rezaei Square, Lorestan University of Medical Sciences
City
Khorramabad
Province
Lorestan
Postal code
6816889468
Approval date
2023-03-15, 1401/12/24
Ethics committee reference number
IR.LUMS.REC.1401.311

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
Pain level is measured by two methods of interview and VAS questionnaire (0-10) at the beginning and end of each cycle during 3 consecutive cycles.
Timepoint
Pain intensity between three consecutive cycles (12 weeks) in different experimental groups
Method of measurement
Pain level is measured by two methods of interview and VAS questionnaire (0-10)

Secondary outcomes

1

Description
Pain level is measured by two methods of interview and VAS questionnaire (0-10) at the beginning and end of each cycle during 3 consecutive cycles.
Timepoint
Pain level is measured by two methods of interview and VAS questionnaire (0-10) at the beginning and end of each cycle during 3 consecutive cycles.
Method of measurement
Pain intensity between three consecutive cycles (12 weeks) in different experimental groups

Intervention groups

1

Description
Intervention group: group receiving a low dose of phytosome made containing anethole and mefenamic acid
Category
Treatment - Drugs

2

Description
Intervention group: the group receiving a moderate dose of phytosome made containing anethole and mefenamic acid
Category
Treatment - Drugs

3

Description
Intervention group: the group receiving a high dose of phytosome made containing anethole and mefenamic acid
Category
Treatment - Drugs

4

Description
Control group: group receiving 0 dose of phytosome made containing anethole and mefenamic acid
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Reproductive health specialist office
Full name of responsible person
Marzieh Rashidipour
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No. 140, Razi Ave. Pajohandeh Blvd, Herbal Research Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Dr.Bahram Rasoulian
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No. 20, Anooshirvan Rezaei Square, Lorestan University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Marzieh Rashidipour
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Nanotechnology
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only part of the data, such as information about the main consequence or similar, can be shared
When the data will become available and for how long
Start the access period 18 months after printing the results.
To whom data/document is available
Data will only be available to researchers working at academic and scientific institutions
Under which criteria data/document could be used
The data will only be used to inform the results of the study
From where data/document is obtainable
Lorestan University of Medical Sciences
What processes are involved for a request to access data/document
Refer to Lorestan University of Medical Sciences, Vice Chancellor of Research and Technology, Research Projects Department, Management of Research Projects Department, 066333120175, Mrs. Sajedi , fax:066333120173 call mrs. zarei 0989167083314
Comments