Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparative study of the effect of hydroalcoholic extract of chamomile and flaxseed oil on pelvic pain, dyspnea and dysmenorrhea in patients with endometriosis

Protocol summary

Study aim

1- Determination of severity of chronic pelvic and dysmenorrhea dysparonychia in chamomile group before and after chamomile capsule administration. 2- Determination of severity of dysmenorrhea, chronic pelvic pain and dysparonychia in flaxseed group before and after flaxseed oil capsule administration. 3- Determination of severity of chronic pelvic pain and dysmenorrhea and dysparonychia in control group before and after placebo capsule administration.

Design

Clinical trial with control group, parallel groups, double blind, randomized, 120 sample size in the sampling phase

Settings and conduct

Clinical trial study is performed at Jihad Infertility Center and Reyhaneh Infertility Center affiliated to Qom University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Exclusion criteria: Any known physical disorders (pelvic inflammatory disease, autoimmune or metabolic disease) and known psychological problems Alcohol and tobacco use Use of supplements Exclusion criteria: Incorrect daily intake and consumption (if used within one hour after using chamomile capsule, flaxseed oil and placebo) Chamomile capsule and flaxseed capsule by patients Unwillingness to continue studying

Intervention groups

Chamomile group: The group that consumes 9 g of chamomile daily (3 g every 8 hours) Flax Seed Group:The group receiving 6 g of flaxseed oil extract (2 g every 8 hours) The placebo group: The group that found 500 mg of avicel in each capsule

Main outcome variables

Severity of dysmenorrhea, chronic pelvic pain, dysparonychia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190625044004N1**
Registration date: **2021-06-28, 1400/04/07**
Registration timing: **retrospective**

Last update: **2021-06-28, 1400/04/07**
Update count: **0**

Registration date

2021-06-28, 1400/04/07

Registrant information

Name

Fatemeh Mohanazadehfalaheih

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3770 6470

Email address

mohana6492@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-01, 1398/09/10

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative study of the effect of hydroalcoholic extract of chamomile and flaxseed oil on pelvic pain, dyspnea and dysmenorrhea in patients with endometriosis

Public title
Comparative study of the effect of chamomile and flaxseed oil on patients with endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Married Pelvic pain dysmenorrhea dysparonia Hypovaccular mass and ultrasound vascular with varying degrees of blood flow velocity And the number of vessels seen in Doppler ultrasoundPatients who referred to the Jihad Infertility Center of the University Insensitivity to chamomile and flaxseed

Exclusion criteria:
Has underlying heart, kidney, liver disease Taking hormonal drugs such as oral contraceptive pills, progesterones

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the limited randomization method of block randomization will be used. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to ensure that the number of samples assigned to each of the study groups is equal in cases where intermediate analyzes are required during the sampling process. The size of all the blocks is equal and in this We will have a three-group trial of 36 blocks of 3. Randomization tool also uses random sequence generation software that these random sequence generation software in addition to simple randomization are able to generate random sequence by blocking method. For concealment, random allocation concealment is used, which is the method used to execute a random sequence on study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with a random sequence in which each of the random sequences created on a card It is registered and the cards are placed in the letter envelopes in order To be. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the sampling, one of the envelopes of the letter is opened and the assigned group of the participant is revealed, based on the order of entry of the eligible participants

Blinding (investigator's opinion)
Double blinded

Blinding description
Starting the treatment cycle, if the patient chooses code A, medication A is given and either B or C is given (for example A recipient of chamomile capsule and B code for flaxseed oil and C code for placebo). The coding is performed by a pharmacist.) The drugs are quite similar in appearance and are unknown to the researcher and patient, and are only known to the pharmacist but are quite similar in appearance. Each medication is packaged in separate packages coded with the letters A, B, and C and provided to research units.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qom University of Medical Sciences

Street address
Shahid Lavasani St, Qom University of Medical Sciences

City
Qom

Province
Ghoum

Postal code
3713649373

Approval date
2019-03-06, 1397/12/15

Ethics committee reference number
IR. MUQ.REC.1397.192

Health conditions studied

1

Description of health condition studied
Endometriosis

ICD-10 code
N80.1

ICD-10 code description
Endometriosis of ovary

Primary outcomes

1

Description
Pain score of people with dysmenorrhea
Timepoint
Measurement of reduction of dysmenorrhea before intervention and one month and two months after intervention After starting Consumption Chamomile and flaxseed oil and placebo
Method of measurement
Using Visual Analogue Scale

2

Description
Pain score of people with chronic pelvic pain
Timepoint
Measurement of reduction of pelvic pain before intervention and one month and two months after intervention After starting Consumption Chamomile and flaxseed oil and placebo
Method of measurement
Using Visual Analogue Scale

3

Description
Pain score of people with dysparonia
Timepoint
Measurement of reduction of dysdisparonia before intervention and one month and two months after intervention After starting Consumption Chamomile and flaxseed oil and placebo
Method of measurement
Using Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Chamomile -Dosage: 9 gr daily Dosage: 2 months- Frequency of use: In three divided doses (3 gr every 8 hours) How to use: Oral capsule - Producer: Pharmacist
Category
Treatment - Drugs

2

Description
Intervention group: Flaxseed - Dosage: 6 gr daily Dosage: 2 months - Frequency: In three divided doses (2 gr every 8 hours) How to use: Oral capsule - Producer: Pharmacist
Category
Treatment - Drugs

3

Description
Control Placebo - Dosage: 3 gr daily Dosage: 2 months - Dosage: In three divided doses (1 gr every 8 hours) How to use: Avicel oral capsule - Manufacturer: Pharmacistgroup:
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Reyhaneh infertility center
Full name of responsible person
Fatemeh Mohanazadeh Fallahieh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Ehsan Sharifipour
Street address
Shahid Lavasani St., Qom University of Medical Sciences and Health Services
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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Fatemeh Mohanazadehflaheieh
Position
Non-faculty coach
Latest degree
Master
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Person responsible for updating data

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Latest degree
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Midwifery
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Email
mohana6492@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
Individual data related to participants
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
It will only be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Items that are in line with the studied variables
From where data/document is obtainable
first name and last name: Fatemeh Mahnazadeh Fallahieh Email: mohana6492@gmail.com

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

After requesting the email, the data will be sent within a week of the applicant's email

Comments