

# 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 Hypovascular mass and ultrasound vascular with varying degrees of blood flow velocity And the number of vessels seen in Doppler ultrasound Patients 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**

Ghous

**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

##### **Street address**

Azar Street

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

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##### **Email**

mohana6492@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Ghous University of Medical Sciences

##### **Full name of responsible person**

Ehsan Sharifipour

##### **Street address**

Shahid Lavasani St., Qom University of Medical Sciences and Health Services

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

+98 25 3285 2720

##### **Email**

Sharifipour.e@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Ghous 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

**Other areas of specialty/work**

Midwifery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ghoum University of Medical Sciences

**Full name of responsible person**

Zohreh kalajinia

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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**Person responsible for updating data****Contact****Name of organization / entity**

Ghoum University of Medical Sciences

**Full name of responsible person**

Fatemeh Mohanazadehflaheieh

**Position**

Non-faculty coach

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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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**

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**