

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of the Effects of Traditional Dosage form Called Hamol-e-Aftimone in Improving Pelvic Pain, Quality Of Life And Ovarian Cyst Size in Endometriosis Patients; A Double-Blind, Placebo-Controlled Clinical Trial

Protocol summary

Study aim

Evaluation of the effect of traditional Dosage form of Hamol-Aftimone in improving pelvic pain, quality of life and ovarian cyst size in endometriosis patients.

Design

It is a double-blind clinical trial controlled with placebo and has two groups of 34 people receiving traditional medicine and placebo, which will be randomized using random block allocation.

Settings and conduct

The patients are selected from those who visit Sari Emam Khomeini Hospital and receive the drug or placebo. The daily pain questionnaire is filled by the patient. At the end of the first and second month, size of ovarian cyst is measured, the amount of NSAIDs and the patient's quality of life are evaluated by the researcher. It should be noted that the patient, physician and researcher are blinded.

Participants/Inclusion and exclusion criteria

1. Women suffering from endometriosis with pelvic pain and ovarian cysts over two cm between 20 and 45.
2. Absence of Müllerian anomaly, fibrosis, adenomyosis and myoma
3. No medication except pain reliever for endometriosis within 6 months before referral
4. The patient's consent to participate in the plan. People who are pregnant or breastfeeding, have severe pain that is resistant to treatment, have acute liver, kidney disease or any malignancy, or have a previous pap smear with intraepithelial pathological changes are not included in the study.

Intervention groups

In the intervention group, patients take the prepared traditional medicine in the form of vaginal suppositories once a day for two months. Also, in the control group, placebo is consumed with the same prescription for two months.

Main outcome variables

Amount of pain, NSAIDs consumption, ovarian cyst size and Quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130911014630N11**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **prospective**

Last update: **2023-08-30, 1402/06/08**

Update count: **0**

Registration date

2023-08-30, 1402/06/08

Registrant information

Name

Mohammad Azadbakht

Name of organization / entity

Mazandaran University of Medical Science

Country

Iran (Islamic Republic of)

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Email address

mazadbakht@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-07-21, 1403/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effects of Traditional Dosage form Called Hamol-e-Aftimone in Improving Pelvic Pain, Quality Of Life And Ovarian Cyst Size in Endometriosis Patients; A Double-Blind, Placebo-Controlled Clinical Trial

Public title

Formulation of "Aftimoon habb and homul" Based on Iranian Traditional Pharmacy, Development of Standardization Method and Evaluation of the effect of homul on improving pelvic pain, quality of life and ovarian cyst size in endometriosis patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 to 45 Endometriosis patients with pelvic pain and ovarian cyst over two centimeters Absence of Müllerian anomaly, fibrosis, adenomyosis and myoma No medication except NSAIDs for endometriosis within 6 months before referral Presence of patient's consent to participate in the study

Exclusion criteria:

pregnancy and lactation Sever and treatment resistant pain which candidates patient for surgery Absence of any acute and serious liver or kidney disease Absence of pap smear with intraepithelial pathological changes No history of any former or being treated malignancy

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation block method will be used. The number of considered blocks is 4. The list of random allocation of patients will only be at the disposal of the project methodologist. In order to hide the random allocation process, random 10-digit codes are written on the paper labels without a specific order and framework, which is the identification number of the relevant treatment and only the project methodologist will be aware of the relevant code. The labels will be stuck on the drug packages in order of the randomization list.

Drug packages will be arranged in the order of the randomization list inside the box. When the doctor declares the eligibility of a patient, the methodologist will provide the patient with the package treatment plan. The person evaluating the intended outcomes is a third person who is unaware of the randomization process and the type of treatment performed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo, which have the same size, color, and smell, are provided in the same containers based on random allocation by both groups, so none of the patients were aware of the assigned treatment and will not be informed until the end of the study. Also, the researcher evaluating the intended outcomes is unaware of the random allocation process and the type of treatment performed. In order to analyze the data, a statistician who is separate from the study process and is unaware of all the processes will be used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Payambar Azam University Complex, 17' Km of Farah Abad Road

City

sari

Province

Mazandaran

Postal code

4847191971

Approval date

2023-07-12, 1402/04/21

Ethics committee reference number

IR.MAZUMS.REC.1402.196

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Amount of pain

Timepoint

At the beginning of the study, then during the study on period days 3 times a day

Method of measurement

Visual Analog scale

Secondary outcomes

1

Description

Size of ovarian cyst

Timepoint

At the beginning of the study, after the first month and after the second month

Method of measurement

Trans-vaginal ultrasound

2

Description

Patient quality of life

Timepoint

At the beginning of the study, after the first month and after the second month

Method of measurement

Quality of life Questionnaire EHP30

3

Description

Painkiller consumption

Timepoint

At the beginning of the study, after the first month and after the second month

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Receiving Homul(Suppository) of Aftimoon

Category

Treatment - Drugs

2

Description

Control group: Receiving Placebo

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Emam Khomeini hospital

Full name of responsible person

Dr. Marziye Zamanian

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Amir Mazandarani Ave,

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Fateme Alizade

Position

Ph D Condidate of traditional pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Latest degree

Ph.D.

Other areas of specialty/work

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Position

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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

No - There is not 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

Not applicable

Title and more details about the data/document

Results from clinical trials

When the data will become available and for how long

2 Month after publishing

To whom data/document is available

Allowed only with the mention of the source.

Under which criteria data/document could be used

For traditional pharmacy researchers

From where data/document is obtainable

Fateme Alizade 09387845915

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

Asking from the resercher

Comments