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

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Name of organization / entity
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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 surgary 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 Madical Sciences

Street address

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

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sari

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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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Sponsors / Funding sources

1

Sponsor
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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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Position
Ph D Condidate of traditional pharmacy

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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