Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Investigating the effect of standard treatment of classical medicine and embedding in controlling dysmenorrhoea and dysparonychia caused by endometriosis in women.

Protocol summary

Study aim
Comparison of standard treatment of classical medicine and embedding in the control of dysmenorrhea and dysparonychia caused by endometriosis in women.

Design
Considering the VAS scale as the primary outcome, the smallest improvement difference based on this scale is -3.9, and based on previous studies, the standard deviation is 1.7 and the difference between the two treatments is 3. The sample size for each group is 44 people, considering The drop rate will be calculated in a sample size of 50 people in each group. To determine the relationship between individual characteristics and the effect of the intervention, multivariate statistical tests including two-way analysis of variance will be used. In addition, sensitivity analyzes will be performed based on the desired subgroups. All analyzes will be performed at a significance level of 5% and a confidence level of 95%. SPSS software version 24 will be used for data analysis. This study will be double-blinded (examiner and analyst) and with limited randomization of block randomization type.

Settings and conduct
Acupuncture Clinic of Imam Reza Hospital

Participants/Inclusion and exclusion criteria
Entry criteria Diagnosis of clinical endometriosis by observing pain and tenderness in the pelvic examination along with endometriosis nodules in the vaginal examination, fixed and immobile uterus and confirmed by ultrasound or MRI (observation of endometriosis cysts and nodules) Diagnosis of grade I-IV endometriosis based on r-ASRM criteria during complaining of dysmenorrhea with EAPP score >30 or >40. Normal prolactin level, normal pap smear Age 18-45 years Informed written consent to participate in the study

Intervention groups
Women with endometriosis aged 18 to 45

Main outcome variables
Dysmenorrhea and dyspareunia; serum level of anti mullerian hormone and antral follicle count (primary outcome); quality of life secondary outcome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121228011912N5**
Registration date: **2023-05-10, 1402/02/20**
Registration timing: **prospective**

Last update: **2023-05-10, 1402/02/20**
Update count: **0**

Registration date
2023-05-10, 1402/02/20

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2023-11-21, 1402/08/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of standard treatment of classical medicine and embedding in controlling dysmenorrhoea and dysparonychia caused by endometriosis in women.

Public title
Investigating the effect of standard treatment of classical medicine and embedding in controlling dysmenorrhea and dyspareunia caused by endometriosis in women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of clinical endometriosis by observing pain and tenderness in the pelvic examination along with endometriosis nodules in the vaginal examination, firm and motionless uterus and confirmed by ultrasound or MRI (observation of endometriosis cysts and nodules) Diagnosis of grade I-IV endometriosis based on r-ASRM criteria during diagnostic laparoscopy during the previous 12 months Dysmenorrhea complaint with EAPP score >30 or >40 normal pap smear Age 18-45 years Informed written consent to participate in the study
Exclusion criteria:
Unwillingness to continue the research Non-adherence to the provided treatment regimen and incorrect or incomplete use of medication Occurrence of any complications attributed to drug use (especially allergies) Endometriosis who were treated with GNRH agonist less than 6 months ago, or danazol or progesterone pills less than 3 months ago, or birth control pills less than one month ago Breastfeeding, pregnancy. Cancers of the uterus, ovaries, cervix and high-grade intraepithelial lesions
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the online site https://www.sealedenvelope.com, random allocation will be placed in two groups: A, classical medicine, and B, embedding. Randomization will be done based on Block Randomization with blocks of 4. The random allocation of 12 blocks of 4 will be as follows. The prepared blocks will be placed in the envelope. One of the envelopes will be randomly selected according to the order of patients' arrival, and based on the obtained blocks, 4 patients will be assigned to two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Using the online site https://www.sealedenvelope.com, random allocation will be placed in two groups: A, classical medicine, and B, embedding. Randomization will be done based on Block Randomization with blocks of 4. The random allocation of 12 blocks of 4 will be as follows. The prepared blocks will be placed inside the envelope. According to the order of patients' entry, one of the envelopes will be randomly selected and based on the obtained blocks, 4 patients will be assigned to two groups. Then, the collaboration, which is blind to the type of interventions, will check all patients in terms of entry and exit criteria, and then Forms and questionnaires are completed and primary and secondary outcomes are determined for those eligible
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences (Research Ethics Committee)
Street address
3rd floor - Abuzar qafari Bulv - Abuzar qafari 38- Ahmad Abad Ave.
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mashhad
Province
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Postal code
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Approval date
2023-04-07, 1402/01/18
Ethics committee reference number
IR.MUMS.REC.1402.020

Health conditions studied

1

Description of health condition studied
dysmenorrhea and dyspareunia caused by endometriosis
ICD-10 code
N80.9
ICD-10 code description

Endometriosis, unspecified

Primary outcomes

1

Description
Dysmenorrhea and dyspareunia
Timepoint
At the beginning of the study (before the start of the intervention) and 3 months later
Method of measurement
It will be evaluated using the EAPP checklist scale

2

Description
Anti-Müllerian hormone serum level and antral follicle count
Timepoint
At the beginning of the study (before the start of the intervention) and 3 months later
Method of measurement
Measurement of anti-Müllerian hormone serum level and antral follicle count by ultrasound

Secondary outcomes

1

Description
Quality of Life
Timepoint
At the beginning of the study (before the start of the intervention) and 3 months later
Method of measurement
Short form of World Health Organization quality of life questionnaire

Intervention groups

1

Description
Intervention group: Embedding in women with dysmenorrhoea and dysparonychia caused by endometriosis in reproductive age. Acupuncture embedding is a new and emerging method developed in the fields of acupuncture and embedding needle. This method has immediate and long-lasting effects on the human body, compensates for the short duration of acupuncture stimulation and reduces the number of times patients visit the doctor.
Category
Treatment - Devices

2

Description
Intervention group: Intervention group: The classical medicine group will be treated with one continuous and regular daily LD pill for a period of three months and from the same day (the first day of the menstrual cycle).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Acupuncture Clinic, Mashhad University of Medical Sciences
Full name of responsible person
Hamidreza Bahrami Taganki
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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
Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Bahrami-Taghanaki

Position

Faculty member

Latest degree

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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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The statistical details of the data will be mentioned in the published article.

When the data will become available and for how long

After finishing research

To whom data/document is available

All those who have access to the published article or with the supervisory permission of the Vice Research of Mashhad University of Medical Sciences

Under which criteria data/document could be used

With the request of the responsible researcher and the consent of the University Research Council and only for survey purposes without any possibility of exploiting the content of the data.

From where data/document is obtainable

After printing the article to the responsible author and before printing, if required by relevant authorities, to the responsible researcher

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

By means if Vice research of Mashhad University of Medical Science

Comments