Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of excision versus ablation in the surgical procedures of superficial endometriosis related to chronic pelvic pain

Protocol summary

Study aim

The comparison of pelvic pain recurrence within 6 and 12 months after treatment of endometriotic lesions with excisional surgery approach versus ablation therapy

Design

Two arm parallel-group randomized trial using Random Allocation software on 60 patients without blindness postoperative care and outcome assessment

Settings and conduct

The patients with endometriosis grades 1 and 2 who are a candidate for surgical treatment And refer to the Educational and Treatment Centers of Alzahra and Shahid Beheshti will be randomly allocated to excisional or ablation treatments of endometriosis using Random Allocation Software. Blinding will not be performed. The patients will be evaluated in terms of recurrence in pelvic pain within 6 and 12 months postoperatively.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Age above 18 years and less than 40 years - Endometriosis grades I and II in laparoscopy - Lacking hormone therapy within the previous three months -Willingness for participation in the study - Chronic pelvic pain for more than 6 months -Normal abdominopelvic, uterine and ovarian ultrasonographic imaging -No medical history of diabetes or hypertension Exclusion criteria: -Lacking gross endometriosis evidence in laparoscopy -Endometriosis grades III and IV in laparoscopy

Intervention groups

Excisional surgery of lesions: Excision of the endometriotic peritoneum by scissors using butterfly method Ablation: Cautery of the endometriotic parts without peritoneal excision

Main outcome variables

Pain score related to dysmenorrhea; to dyspareunia; Dysschesia; non-menstruation time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200518047489N1**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-02, 1399/03/13**
Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

Forough Momeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3444 7707

Email address

forough.momeni@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2020-09-22, 1399/07/01

Trial completion date

2020-09-22, 1399/07/01

Scientific title

The comparison of excision versus ablation in the surgical procedures of superficial endometriosis related to chronic pelvic pain

Public title
Investigation of excisional surgery versus ablation for the treatment of chronic pelvic pain in endometriosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years and less than 40 years Lacking hormone therapy within the previous three months Willingness for participation in the study Chronic pelvic pain for more than 6 months Normal abdominopelvic, uterine and ovarian ultrasonographic imaging No medical history of diabetes or hypertension
Exclusion criteria:
Lacking gross endometriosis evidence in laparoscopy Endometriosis grades III and IV in laparoscopy
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Each of the patients is provided with a particular number using Random Allocation software if the number is odd, the patient will be allocated to the excisional surgery and if even, they will be allocated to the ablation therapy.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezarjarib Avenue
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-03-16, 1398/12/26
Ethics committee reference number
IR.MUI.MED.REC.1398.732

Health conditions studied

1

Description of health condition studied
Endometriosis
ICD-10 code
N80
ICD-10 code description
Endometriosis

Primary outcomes

1

Description
Pain score due to dysmenorrhea
Timepoint
At baseline, within 6 months and within 12 months
Method of measurement
Visual analogue scale questionnaire

2

Description
Dysparonia
Timepoint
At baseline, within 6 months and within 12 months
Method of measurement
Visual analogue scale questionnaire

3

Description
Dyschezia
Timepoint
At baseline, within 6 months and within 12 months
Method of measurement
Visual analogue scale questionnaire

4

Description
Pain in non-menstrual time
Timepoint
At baseline, within 6 months and within 12 months
Method of measurement
Visual analogue scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Excisional surgery: The excision of endometriotic peritoneum based on butterfly method using scissors
Category
Treatment - Surgery

2

Description
Ablation therapy: Cautery of the endometriotic lesions without the excision of affected peritoneum
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Forough Momeni
Street address
Shohaday-e-Sofeh Avenue
City
Isfahan
Province
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Postal code
8174675731
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forough.momeni@gmail.com

2

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Forough Momeni
Street address
Shahid Motahhari Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mojgan Mortazavi
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mortazavi@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Forough Momeni
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

No - There is not 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

The data are accessible if the professor permits

When the data will become available and for how long

Following the publication of the paper, the data are accessible if the professor permits

To whom data/document is available

the people who have a proposal related to the published article

Under which criteria data/document could be used

For the publication of a new article related to this study

From where data/document is obtainable

To the professor

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

Using an email to consult with the professor

Comments