

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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

Isfahan

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

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

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

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3236 7001

Email

forough.momeni@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mojgan Mortazavi

Street address

Hezar Jarib Avenue

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

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

Street address

Hezar jarib Avenue

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3444 7707

Fax

Email

forough.momeni@gmail.com

Person responsible for scientific 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

Street address

Hezar jarib Avenue

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3444 7707

Fax

Email

forough.momeni@gmail.com

Person responsible for updating data

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

Street address

Hezar jarib Avenue

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3444 7707

Fax

Email

forough.momeni@gmail.com

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