Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Safety and efficacy of Radiofrequency ablation of abdominal wall endometriosis

Protocol summary

Study aim

General aims: To determine the safety and effectiveness of Radiofrequency ablation (RFA) of abdominal wall endometriosis (AWE) Specific aims: 1. Evaluation of the safety of RFA of AWE 2. Evaluation of the effectiveness of RFA of AWE in reducing the volume of the lesions and pain caused by AWE lesions within 6 months after treatment. 4. Determining the rate of recurrence and complications caused by RFA of AWE within 6 months after the treatment.

Design

The study is a phase 2 clinical trial with 10 patients without a control group.

Settings and conduct

In this phase 2 clinical trial, patients with abdominal wall endometriosis who were referred to Imam Hussein Hospital from November 2022 for whom surgical treatment was not suitable or the patient personally refused to accept surgical treatment, after understanding all aspects of the treatment including the experimental nature of the treatment method, possible risks, and complications and obtaining written consent, are treated by Radiofrequency ablation for AWE lesions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Abdominal Wall Endometriosis (AWE) diagnosis no history of abdominal wall surgery over the past three months patients without severe comorbidities, such as hypertension or diabetes patients could tolerate 1-2 hours under general anesthesia Exclusion criteria: Patients with more than 1 AWE lesion AWE lesion volume of over 50 cc Past surgical history of resection of AWE Past medical history of heart failure Allergy to cephalexin and lidocaine

Intervention groups

After hospitalization, the patient is subjected to radiofrequency ablation of abdominal wall endometriosis lesions under general anesthesia.

Main outcome variables

The volume of abdominal wall endometriosis lesions before and after treatment; The score of pain in the lesion site before and after treatment

General information

Reason for update

During the study, it was necessary to modify the inclusion and exclusion criteria for a group of patients with specific clinical criteria due to the differences in the patients. So the results of this study could be reliable for patients with these criteria and further studies could evaluate the efficacy of this method in other populations.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220219054066N1**
Registration date: **2022-09-29, 1401/07/07**
Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**
Update count: **1**

Registration date

2022-09-29, 1401/07/07

Registrant information

Name
Ali Forouzannia

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2613 2119

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s.ali.forouzannia@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-27, 1401/08/05

Expected recruitment end date
2022-11-26, 1401/09/05
Actual recruitment start date
2022-10-27, 1401/08/05
Actual recruitment end date
2022-12-15, 1401/09/24
Trial completion date
2023-06-22, 1402/04/01

Scientific title
Safety and efficacy of Radiofrequency ablation of abdominal wall endometriosis

Public title
Radiofrequency ablation of abdominal wall endometriosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Abdominal Wall Endometriosis diagnosis no history of abdominal wall surgery over the past three months patients without severe comorbidities, such as hypertension or diabetes patients could tolerate 1-2 hours under general anesthesia
Exclusion criteria:
Patients with more than 1 abdominal wall endometriosis lesion Abdominal wall endometriosis lesion volume of over 50 cc Past surgical history of resection of abdominal wall endometriosis Past medical history of heart failure Allergy to cephalexin and lidocain
Age
From **18 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **10**
Actual sample size reached: **10**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Avicenna Research Institute
Street address
Avicenna Research Institute, Shahid Beheshti University, Tehran
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2022-09-06, 1401/06/15
Ethics committee reference number
IR.ACECR.AVICENNA.REC.1401.006

Health conditions studied

1

Description of health condition studied
Abdominal wall endometriosis
ICD-10 code
N80.9
ICD-10 code description
Endometriosis, unspecified

Primary outcomes

1

Description
Pain score on Visual Analogue Scale
Timepoint
Pain score at the beginning of the study and 30, 90 and 180 days after treatment
Method of measurement
Visual Analogue Scale

2

Description
The volume of the lesions in abdominal Ultrasound
Timepoint
The volume of the lesions at the beginning of the study and 30, 90 and 180 days after treatment
Method of measurement
Abdominal ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
After determining the volume of the lesions with ultrasound, the patients with receive general anesthesia and local anesthesia will be achieved with a

subcutaneous injection of 1% Lidocaine. Then Radiofrequency ablation will be performed. The heating process will last 60-120 seconds, and the temperature will reach 90-95 degrees. After the ablation of each section, the transducer will move, and a nearby section will be treated similarly until the entire lesion is ablated. The patient will be closely monitored in the recovery room for six hours, and if no complications occurred, they will be sent home the same night. Prophylactic antibiotic therapy is Cephalexin 500 mg every six hours for three days.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital

Full name of responsible person

Seyed Ali Forouzannia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Ramin Ghahremanzadeh

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Avicenna research institute, Shahid Beheshti University, Tehran, Iran

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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

Iranian academic center for education culture and research

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Forouzannia

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Radiology

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Person responsible for scientific inquiries

Contact

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Position

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Specialist

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Person responsible for updating data

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Position
Medical student
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
Yes - There is 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
Publishable data from this study include the following: age of patients, pain level before and after treatment based on visual analog scale, the volume of abdominal wall endometriosis lesions before and after treatment
When the data will become available and for how long
The access to data is available 6 months after the project results are published.
To whom data/document is available
The data obtained from this study will be available to researchers who intend to design a similar study.
Under which criteria data/document could be used
It is possible to use the data to assess the response to treatment and perform analyzes that compare the means of the variables.
From where data/document is obtainable
Researchers contact Seyed Ali Forouzannia through the email below. s.ali.forouzannia@gmail.com
What processes are involved for a request to access data/document
The researcher must first send the proposal and approval of the ethics committee to Seyed Ali Forouzannia, and after review, the information will be provided to him within one month.
Comments