Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating myometrial thickness and scar vascularity compared to healthy myometrium using Doppler ultrasound in patients undergoing hysteroscopic myomectomy with and without preservation of pseudocapsule.

Protocol summary

Study aim
Investigating the effect of pseudocapsule removal on myometrial thickness and scar vascularity in patients undergoing hysteroscopic myomectomy using Doppler ultrasound

Design
The clinical trial has a control group with a factorial group, double-blind, randomized on 50 patients, and random assignment software is used for randomization.

Settings and conduct
The population under study are patients undergoing hysteroscopic myomectomy in the age range of 18 to 45 years who referred to Shahid Beheshti Medical Training Center in 1402. The patients are randomly divided into two groups, preservation and removal of myoma pseudocapsule. The classification of patients is unknown

Participants/Inclusion and exclusion criteria
Inclusion criteria include the age between 18-45 years of women who have Type 1 myoma. Only one myoma and that it has an indication for surgery. The size of the myoma is less than 5 cm. The exclusion criteria for women who have more than one myoma and myoma other than type 1. They have cervicitis and are pregnant

Intervention groups
In the intervention group, the pseudocapsule myoma is removed with a resectoscope during the operation, and in the control group, the pseudocapsule is preserved.

Main outcome variables
Examination of the surgical site scar

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230519058228N1**
Registration date: **2023-05-23, 1402/03/02**
Registration timing: **prospective**

Last update: **2023-05-23, 1402/03/02**
Update count: **0**

Registration date
2023-05-23, 1402/03/02

Registrant information

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Maryam Hashemi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-10, 1402/03/20

Expected recruitment end date
2023-10-22, 1402/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating myometrial thickness and scar vascularity compared to healthy myometrium using Doppler ultrasound in patients undergoing hysteroscopic

myomectomy with and without preservation of pseudocapsule.

Public title
The effect of preserving the myoma pseudocapsule wall in repairing the surgical site in patients undergoing hysteroscopic myomectomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women between 18 and 45 years old who are candidates for hysteroscopic myomectomy due to a symptomatic Figo submucosal myoma. The size of myoma should be less than 5 cm and the number of myoma should be one

Exclusion criteria:
Women who have more than one myoma and myoma other than type 1. Women who have servicitis and are pregnant.

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Using random allocation software, 50 selected patients are divided into two groups: removal and preservation of myoma pseudocapsule during hysteroscopic myomectomy. In the said software, the total number of sample volume (50 people) and the number of groups (2 groups) are entered into the software. The output of the software includes a list that randomly distributes the numbers 1 to 50 in two groups. Patients are distributed in two groups according to the time of referral in the order of the mentioned list so that the sample volume reaches the required number in each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is conducted in a two-way blind method. In such a way that the patients are unaware of the type of operation (preserve or removal of myoma pseudocapsule); Also, the outcome assessor (sonographer) does not know whether to preserve or remove the myoma pseudocapsule.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی اصفهان

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Isfahan Hezar Jerib St. Isfahan University of Medical Sciences and Health Services

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8174673461

Approval date
2023-05-17, 1402/02/27

Ethics committee reference number
IR.MUI.MED.REC.1402.080

Health conditions studied

1

Description of health condition studied
submucousal myoma

ICD-10 code
D25.0

ICD-10 code description
Submucous leiomyoma of uterus

Primary outcomes

1

Description
Examination of myomectomy scar

Timepoint
3 months after the operation

Method of measurement
Transvaginal ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: women with submucousal myoma Fig. 1 During the shaving of the myoma with a resectoscope, the resectoscopy is stopped as soon as the pseudocapsule is reached and the pseudocapsule is kept in place .Three months after the operation using Doppler ultrasound, scar thickness, scar vascularity And the

existence of a heterogeneous mass in the operation site is checked.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Shahid Beheshti hospital

Full name of responsible person

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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

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

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Position

Assistant Professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The data will not be shared separately, but the results of their analysis will be shared in the article
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available