

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the features of the uterine scar after Laparoscopy vs laparoscopy-assisted myomectomy, using color Doppler ultrasound imaging

Protocol summary

Study aim

Comparison of the features of the uterine scar after Laparoscopy vs laparoscopy-assisted myomectomy, using color Doppler ultrasound imaging

Design

This study was designed as a quasi-experimental clinical trial in which 92 eligible women will be included in the study.

Settings and conduct

According to inclusion and exclusion criteria, patients will be selected for myomectomy. Pre-operation imaging will be done by pelvic MRI and ultrasound. In all cases, a 10 mm trocar will introduce at the umbilicus. After creation of pneumoperitoneum, one 10 mm suprapubic and two 5 mm lateral trocars will be inserted into the abdominal wall. Diluted vasopressin (20 U in 100 cc normal saline) will be injected between the myoma and the serosa for controlling hemorrhage. A transverse incision by monopolar needle (60 w cut mode) will be done on the myoma site. The myoma will be enucleated by using scissors and applying traction and countertraction. After complete removal of the myoma, myomectomy site will be sutured with the laparoscopic or laparoscopy-assisted method as described previously. The choice of suturing method depends on the patient's condition and availability of morcellator. All the procedures will be performed by the same laparoscopic surgery team of Arash Hospital in Tehran and the variables studied will be recorded on the checklist. 3 months after surgery, the patients will be followed and ultrasound imaging will be done by the same sonographer who is unaware of the surgical procedure.

Participants/Inclusion and exclusion criteria

Women of reproductive age with type 2 to 6 uterine myomas If there are no changes in favor of sarcoma or contraindications for laparoscopy, will be included in this study.

Intervention groups

Group I: Laparoscopic myomectomy Group II: Laparoscopy-assisted myomectomy

Main outcome variables

Myometrial thickness; blood flow; and hematoma in the site of the uterine scar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110530006640N5**

Registration date: **2018-09-30, 1397/07/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-30, 1397/07/08**

Update count: **0**

Registration date

2018-09-30, 1397/07/08

Registrant information

Name

Zahra Asgari

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the features of the uterine scar after Laparoscopy vs laparoscopy-assisted myomectomy, using color Doppler ultrasound imaging

Public title

Uterine scar after Laparoscopy vs laparoscopy-assisted myomectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Reproductive ages (20 - 45 years old) Patient's desire to maintain the uterus Type 2 to 6 myomas The maximum number of myomas: 1 Size of Myoma: less than 10 cm

Exclusion criteria:

Changes in favor of sarcoma in MRI Laparoscopy contraindication History of myomectomy or Classic Cesarean section

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Sonographer responsible for the assessment of uterine scar will be unaware of the type of surgery performed in patients. Also, the statistical analyzer will be unaware of the type of intervention performed in the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Research and Technology Dept, Sixth Floor of Central University Building, Corner of Quds Street, Keshavarz Blvd, Tehran, Iran

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1417653761

Approval date

2018-05-03, 1397/02/13

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.084

Health conditions studied**1****Description of health condition studied**

Leiomyoma of uterus

ICD-10 code

D25

ICD-10 code description

Leiomyoma of uterus

Primary outcomes**1****Description**

myometrial thickness at the site of the uterine scar and intact myometrium

Timepoint

3 Months after myomectomy

Method of measurement

Samsung WS80A Ultrasound Machine (both vaginal and abdominal probes)

2**Description**

blood flow at the site of the uterine scar and intact myometrium

Timepoint

3 Months after myomectomy

Method of measurement

doppler ultrasound

3**Description**

Hematoma size

Timepoint

3 Months after myomectomy
Method of measurement
Samsung WS80A Ultrasound Machine (both vaginal and abdominal probes)

Secondary outcomes

1

Description

Operative time

Timepoint

at the time of operation

Method of measurement

Timer

2

Description

Hemoglobin concentration

Timepoint

Pre and post operation

Method of measurement

CBC Test

3

Description

Blood transfusion

Timepoint

During or post operation

Method of measurement

check list

4

Description

length of hospital stay

Timepoint

Time interval between operation and discharge

Method of measurement

check list

Intervention groups

1

Description

Intervention group 1: Myomectomy site will be sutured with vicryl 1-0 continuously in two or three layers according to defects depth, and, the serosa will be sutured with vicryl 2-0 laparoscopically.

Category

Treatment - Surgery

2

Description

Intervention group 2: After opening the abdominal wall about 4 cm and introducing the retractor (Alexis) the myometrium and serosa will be sutured in the same manner and with the same material as the first group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women's Hospital

Full name of responsible person

Dr.Zahra Asgari

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Sponsors / Funding sources

1

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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

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
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Position
assistant proffesor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available