

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Intrauterine synechiae after myomectomy; laparotomy versus laparoscopy

Protocol summary

Summary

Background: Leiomyomata is the most frequent gynecological neoplasm. One of the major complications of myomectomy is intrauterine adhesion (synechiae). Objective: To evaluate and compare the rate and severity of synechiae formation after myomectomy by laparotomy and laparoscopy. Design: non-randomized interventional trial Materials and Methods: Participants: All married fertile women who had undergone myomectomy (type 3-6 interamural and subserosal fibroids) via laparotomy and laparoscopy in Tehran's Arash Hospital. The exclusion criteria: receiving GnRH analogous, a history of uterine surgery, the presence of systemic conditions which increase the occurrence rate of synechiae such as genital tuberculosis, endometritis or post-operative fever of unknown origin, no desire to include in the survey, patients for whom laparoscopy was contra-indicated due to the myoma size or other parameters. Intervention: Three months after the operation, hysteroscopy was performed in all patients. Essential variants: The occurrence rate and severity of intrauterine synechiae, and its relationship with type, number and location of myomas in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014123020486N1**

Registration date: **2015-02-15, 1393/11/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-15, 1393/11/26

Registrant information

Name

Leili Hafizi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2608

Email address

hafizil@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Tehran University of Medical Sciences

Expected recruitment start date

2013-07-06, 1392/04/15

Expected recruitment end date

2015-07-06, 1394/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intrauterine synechiae after myomectomy; laparotomy versus laparoscopy

Public title

Evaluation intrauterine adhesion after uterine myoma surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all of the married fertile women who had undergone myomectomy; having intra-mural and sub-serosal fibroids; types 3-6 (according to FIGO classification). Exclusion criteria: receiving GnRH

analogous; a history of uterine surgery; the presence of systemic conditions which increase the occurrence rate of synechiae such as genital tuberculosis, endometritis or post-operative fever of unknown origin; no desire to include in the survey; patients for whom laparoscopy was contra-indicated due to the myoma size or other parameters.

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Tehran University of Medical Sciences

Street address

Central Organization of Tehran University of Medical Sciences, Across from Ghoda Street, Keshavarz Boulevard, Tehran

City

Tehran

Postal code

Approval date

2013-07-02, 1392/04/11

Ethics committee reference number

92-01-39-22191

Health conditions studied

1

Description of health condition studied

intrauterine synechia

ICD-10 code

N85.5

ICD-10 code description

Other specified noninflammatory disorders of uterus

Primary outcomes

1

Description

Intrauterine synechia

Timepoint

3 months after myomectomy

Method of measurement

According to the modified classification of the European Society of Gynecological Endoscopy (ESGE)

Secondary outcomes

1

Description

Evaluation relationship between type, size and location of myoma with frequency and severity of intrauterine adhesion

Timepoint

3 months after myomectomy

Method of measurement

Based on FIGO classification

Intervention groups

1

Description

All patients in intervention group underwent myomectomy by laparoscopy method. Surgeries were performed in the follicular phase of menstrual cycle (except for those with metrorrhagia). Surgery was performed under generalized anesthesia. Hysteroscopy was initially performed in order to determine the type of myoma and detect the intra-uterine pathology; if there was any, the patient would be excluded of the survey. The myomectomy surgical technique was similar by control group (laparotomy). For uterine suturing, the 1 and 0 vicryl suture was used. In the case of endometrial opening, 3 layers and in other cases 2 layers were used.

Category

Treatment - Surgery

2

Description

All patients in control group underwent myomectomy by laparotomy method. Surgeries were performed in the follicular phase of menstrual cycle (except for those with metrorrhagia). Surgery was performed under generalized anesthesia. Hysteroscopy was initially performed in order to determine the type of myoma and detect the intra-uterine pathology; if there was any, the patient would be excluded of the survey. The myomectomy surgical technique was similar by intervention group (laparoscopy). For uterine suturing, the 1 and 0 vicryl suture was used. In the case of endometrial opening, 3 layers and in other cases 2 layers were used.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash Women's Hospital

Full name of responsible person

Zahra Asgari

Street address

Baghdarnia Street

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Deputy of Tehran University of Medical Sciences

Full name of responsible person

Nahid Mostofi

Street address

Sixth floor, Central Organization of Tehran University of Medical Sciences, Across from Ghoda Street, Keshavarz Boulevard, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Deputy of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Zahra Asgari

Position

Associated Professor

Other areas of specialty/work**Street address**

Arash Women's Hospital, Laparoscopy Department

City

Tehran

Postal code**Phone**

+98 21 7773 3934

Fax**Email**

dr.zahra.asgari@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Leili Hafizi

Position

Associated Professor

Other areas of specialty/work**Street address**

Gynecology Department, Imam Reza Hospital, Ebnesina Street, Mashad

City

Mashhad

Postal code**Phone**

+98 51 3802 2608

Fax**Email**

hafizil@mums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Leili Hafizi

Position

Associated Professor

Other areas of specialty/work**Street address**

Gynecology Department, Imam Reza Hospital, Ebnesina Street, Mashad

City

Mashhad

Postal code**Phone**

+98 51 3802 2608

Fax**Email**

hafizil@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty