

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of outcomes after laparoscopic myomectomy with morcellation versus laparotomy myomectomy without morcellation

Protocol summary

Summary

This is a non-randomized clinical trial (quasi-experimental) that aims to compare the results of the peritoneal washing and peri-operative outcomes in laparoscopic myomectomy with morcellation versus laparotomy myomectomy without morcellation in patients whom referred to Arash Hospital for myomectomy. We include all woman who meet the established criteria for myomectomy in Arash Hospital. Subjects should be aged between 18 and 45 years old without known or suspected history of cancers and have Normal menstrual cycle. in the case of abnormal uterine bleeding , an endometrial biopsy will be performed. in the laparoscopic myomectomy group, patients who have a history of uterine, ovary or colon cancer in her own or her first degree relatives diagnosed under the age of 50 years, will be excluded. All participants in laparoscopy group will provide written informed consent recommended by FDA panel outlining the risks of morcellation and of unsuspected malignant myoma (In this case, the malignancy can be diffused and the prognosis will be significantly worsened) . Sample size: 144 (72 in the laparoscopic (interventional) group and 72 in the laparotomy group (control)) in the laparoscopic group abdominal washing will be done in two steps. First step after myomectomy and suturing the myoma bed, and the second step after the morcellation will be done. In the laparotomy group, washings step will be performed one time after the end of the myomectomy and closing the bed, the uterus is returned to the pelvis. Pathological assessment for detecting The presence of spindle cells in peritoneal washings will perform by using cell block technique. Peri-operative outcomes including the duration of surgery, pre and postoperative hemoglobin levels, hospitalization time and re-admission will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707156640N2**

Registration date: **2017-08-04, 1396/05/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-04, 1396/05/13

Registrant information

Name

Zahra Asgari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 8755

Email address

asgariza@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of outcomes after laparoscopic myomectomy with morcellation versus laparotomy myomectomy without morcellation

Public title

comparison of outcomes after laparoscopic myomectomy with morcellation versus laparotomy myomectomy without morcellation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: subjects should be aged between 18 and 45 years old without known or suspected history of cancers and have Normal menstrual cycle Exclusion criteria: (in laparoscopy group) : a history of uterine, ovary or colon cancer in her own or her first degree relatives diagnosed under the age of 50 years

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

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

Tehran Province, Tehran, District 6, Pour Sina St

City

Tehran

Postal code

Approval date

2017-06-24, 1396/04/03

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.2714

Health conditions studied

1

Description of health condition studied

Leiomyoma of uterus

ICD-10 code

D25

ICD-10 code description

benign neoplasms of uterus with morphology code M889 and behaviour code /0 fibromyoma of uterus

Primary outcomes

1

Description

duration of surgery

Timepoint

during intervention

Method of measurement

Hours and minutes

2

Description

result of pertoneal washing pathological assessment

Timepoint

after intervention

Method of measurement

presence of spindle cells

3

Description

Blood loss

Timepoint

pre and post operative

Method of measurement

Hemoglobin level

4

Description

Hospitalization time

Timepoint

after intervention

Method of measurement

Check list

5

Description

complications during operation

Timepoint

during intervention

Method of measurement

Bowel, bladder or ureter injury or hysterectomy (checklist)

Secondary outcomes

1

Description

readmission for myomectomy

Timepoint

after intervention

Method of measurement

check list

Intervention groups

1

Description

laparoscopic myomectomy

Category

Treatment - Surgery

2

Description

laparotomy myomectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women Hospital

Full name of responsible person

Dr.Maryam Hashemi

Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences , Deputy of Research

Full name of responsible person

Dr. Akbar Fotohi

Street address

Qods St, Keshavarz Blvd

City

Tehran

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 , Deputy of Research

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

Arash Women 's Hospital

Full name of responsible person

Dr . Maryam Hashemi

Position

laparoscopy fellowship Student

Other areas of specialty/work

Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway

City

Tehran

Postal code

Phone

+98 21 7771 9922

Fax

Email

nfaridi@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arash Women 's Hospital

Full name of responsible person

Dr. Zahra Asgari

Position

Associate Professor

Other areas of specialty/work

Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway,

City

Tehran

Postal code

Phone

00219877719922

Fax

Email

asgariza@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arash Women 's Hospital, Rashid Ave, Resalat Highway,

Full name of responsible person

Arezoo Maleki Hajiagha

Position

MS , Employee of research development center

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

Arash Women 's Hospital, Rashid Ave, Resalat Highway

City

Tehran

Postal code**Phone**

00

Fax**Email**

arezoomaleki.h@yahoo.com

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