

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy and complications of uterine artery embolization with laparotomy myomectomy in the treatment of uterine fibroids

Protocol summary

Study aim

Comparison of the efficacy and complications of uterine artery embolization with laparotomy myomectomy in the treatment of uterine fibroids

Design

Randomized, non-Controlled, Single-blinding clinical trial, with the parallel groups, Phase 2 on 80 patients

Settings and conduct

In this study, 80 patients with uterine myomas who referred to Al-Zahra and Shahid Beheshti Hospitals in Isfahan, will be included in the study and will be randomly divided into two groups. One group of patients undergoes myomectomy laparotomy and the other group undergoes uterine artery embolization. Then their pain, bleeding, and decrease in hemoglobin will be checked in two groups.

Participants/Inclusion and exclusion criteria

The patients who are consent to participate in the study, aged between 30 and 45 years old, who have completed fertility and are unwilling to fertility, with a diagnosis of symptomatic uterine myoma without responding to supportive measures, are included in the study. Suspected malignancy based on medical imaging, failure to perform previous endometrial sampling to rule out malignancy, pregnancy, acute pelvic inflammatory disease, and sensitivity to contrast media, are exclusion criteria.

Intervention groups

Intervention group 1: Patients in this group undergo laparotomy myomectomy. Intervention group 2: Patients in this group undergo uterine artery embolization.

Main outcome variables

Pain; bleeding; decreased hemoglobin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N19**

Registration date: **2021-01-03, 1399/10/14**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-03, 1399/10/14**

Update count: **0**

Registration date

2021-01-03, 1399/10/14

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and complications of uterine

artery embolization with laparotomy myomectomy in the treatment of uterine fibroids	
Public title	Evaluation of the efficacy and complications of uterine artery embolization with laparotomy myomectomy in the treatment of uterine fibroids
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Consent to participant in the study Aged between 30 and 45 years old Completion of fertility and unwillingness to fertility Diagnosis of symptomatic uterine myoma without response to supportive measures Exclusion criteria: Suspected malignancy based on medical imaging Failure to perform previous endometrial biopsy to rule out malignancy Pregnancy Acute pelvic inflammatory disease Sensitivity to contrast medium
Age	From 30 years old to 45 years old
Gender	Female
Phase	2
Groups that have been masked	• Participant • Outcome assessor • Data analyser
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, 80 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study groups.
Blinding (investigator's opinion)	Single blinded
Blinding description	In this study, due to differences in surgery, the researcher is aware of the types of treatment for the two groups. However, the patient due to the lack of consciousness and the person evaluating the patient's hemodynamic parameters and the data analyst, will not have any information about the two groups.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Isfahan University of Medical Sciences
Street address	Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City	Isfahan
Province	Isfahan
Postal code	8179964167
Approval date	2019-10-09, 1398/07/17
Ethics committee reference number	IR.MUI.MED.REC.1398.357
Health conditions studied	
<u>1</u>	
Description of health condition studied	Uterine Myoma
ICD-10 code	D25.9
ICD-10 code description	Leiomyoma of uterus, unspecified
Primary outcomes	
<u>1</u>	
Description	Pain score
Timepoint	10 days, two months, six months, and twelve months after surgery
Method of measurement	Visual Analog Scale (VAS)
<u>2</u>	
Description	Bleeding
Timepoint	10 days, two months, six months, and twelve months after surgery
Method of measurement	Observation
<u>3</u>	
Description	Hemoglobin
Timepoint	10 days, two months, six months, and twelve months after surgery

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Patients in this group undergo myomectomy. In this method, the patient is hospitalized the night before the operation and receives intestinal operation preparation. He fasts from 12 o'clock at night and receives serum. And prepares for laparotomy myomectomy and after preparation, undergoes laparotomy myomectomy.

Category

Treatment - Surgery

2**Description**

Intervention group 2: Patients in this group undergo uterine artery embolization. In this method, the patient goes to the angiography department on an empty stomach and submits the results of the tests he performed the day before, along with an ECG and an image of the lungs (which are necessary for the operation) to the secretary of the angiography department. After verification of the records, the patient is prepared for injection and the anesthetist injects the patient with the necessary amount of sedative. The area of the body where the catheter is to be inserted is repaired and disinfected and the surgical bag is covered. Next, the catheter entry site, which is usually the groin, is anesthetized. The catheter then enters the artery under the guidance of an X-ray and is placed in the groin area. The blocker substance is then released in turn into the right and left uterine arteries. In the end, only a small hole remains on the skin. Finally, the catheter is removed from the artery and the pressure is taken to prevent bleeding from the perforated area. In this method, there is no need for sutures and the patient can be discharged if the clinical condition stabilizes.

Category

Treatment - Surgery

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

Al-Zahra Hospital

Full name of responsible person

Zahra Allameh

Street address

Soffe Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

z-allameh@med.mui.ac.ir

2**Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

Full name of responsible person

Leila Mousavi Seresht

Street address

Motahari Street.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3234 6338

Email

lmousavi.lm@gmail.com

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

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

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

No

Title of funding source

Isfahan 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
Zahra Allameh
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Department of Obstetrics and Gynecology, Al-Zahra
Hospital, Sofeh Blvd., Tohid Street
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
z-allameh@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Allameh
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Department of Obstetrics and Gynecology, Al-Zahra
Hospital, Sofeh Blvd., Tohid Street
City

Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
z-allameh@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Soheila Afzali
Position
Non-faculty specialist physician
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Department of Obstetrics and Gynecology, Al-Zahra
Hospital, Sofeh Blvd., Tohid Street
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
Dr-afzali-soheyla@yahoo.com

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

There is no further information

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