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

1

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
Isfehan
Postal code
8179964167
Approval date
2019-10-09, 1398/07/17
Ethics committee reference number
IR.MUI.MED.REC.1398.357

Health conditions studied

1

Description of health condition studied
Uterine Myoma
ICD-10 code
D25.9
ICD-10 code description
Leiomyoma of uterus, unspecified

Primary outcomes

1

Description
Pain score
Timepoint
10 days, two months, six months, and twelve months after surgery
Method of measurement
Visual Analog Scale (VAS)

2

Description
Bleeding
Timepoint
10 days, two months, six months, and twelve months after surgery
Method of measurement
Observation

3

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
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Province
Isfehan
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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
Isfehan
Postal code
8174673461
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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.
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8174673461
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+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

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Department of Obstetrics and Gynecology, Al-Zahra Hospital, Sofeh Blvd., Tohid Street

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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

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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

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8174675731

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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