

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The study of efficacy and complications of uterine artery embolization in patients with symptomatic uterine fibroids

Protocol summary

Summary

The purpose of this study is to evaluate the efficacy and complications of uterine artery embolization in patients with symptomatic uterine fibroids. This study is a clinical trial which is not blinded. 97 women with symptomatic uterine fibroids who referred to Imam Reza hospital or maternity clinics are selected through available method. Before treatment, the patients are imaged with MRI and the size, location, and type of fibroids are determined, as well as sonography is performed to determine the uterine volume and a blood sample is taken to check CBC diff, Bun / Cr, PTT / PT. Then a Cobra 5 F catheter enters into the common femoral artery through a small incision on the skin of the groin and is placed in the distal of uterine artery where the artery is became transverse and the right and left uterine arteries are catheterized selectively and embolic material is injected into these arteries, which leads to arteries blockage. Then, the catheter is removed after 60 minutes and the site is packed for 6 hours. The patient is controlled from bleeding of the catheterization site for one night and then can be discharged. The patients are evaluated 3, 6 and 12 months after embolization (UAE) with MRI, ultrasound and questionnaire in terms of response to treatment. Inclusion criteria: written consent of the patient; women with symptomatic uterine fibroids; candidate of hysterectomy or myomectomy. Exclusion criteria: no menopause, ovarian tumors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012714333N16**

Registration date: **2014-02-12, 1392/11/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-12, 1392/11/23

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-09-11, 1392/06/20

Expected recruitment end date

2014-08-11, 1393/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of efficacy and complications of uterine artery embolization in patients with symptomatic uterine fibroids

Public title

The study of efficacy and complications of uterine artery embolization in patients with symptomatic uterine fibroids

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: written consent of the patient; women with symptomatic uterine fibroids; candidate of hysterectomy or myomectomy. Exclusion criteria: no menopause, ovarian tumors.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **97**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Postal code

Approval date
2012-12-29, 1391/10/09

Ethics committee reference number
45277/7/420/پ

Health conditions studied

1

Description of health condition studied
utrine fibroids and bleeding

ICD-10 code
N85.8

ICD-10 code description
Other specified noninflammatory disorders of uterus

Primary outcomes

1

Description
Type of fibroids

Timepoint
Baseline and 3, 6 and 12 months after embolization (UAE)

Method of measurement
MRI

2

Description
Uterine size

Timepoint
Baseline and 3, 6 and 12 months after embolization (UAE)

Method of measurement
Sonography

3

Description
Clinical symptoms

Timepoint
3, 6 and 12 months after embolization (UAE)

Method of measurement
Based on questionnaire

4

Description
Fibroid size

Timepoint
Baseline and 3, 6 and 12 months after embolization (UAE)

Method of measurement
MRI

5

Description
Permanent amenorrhea

Timepoint
Baseline and 3, 6 and 12 months after embolization (UAE)

Method of measurement
Asking the patient

6

Description
Continuous vaginal discharge

Timepoint
3, 6 and 12 months after embolization (UAE)

Method of measurement
Asking the patient

7

Description

Recurrence of fibroids
Timepoint
3, 6 and 12 months after embolization (UAE)
Method of measurement
MRI

Secondary outcomes

empty

Intervention groups

1

Description

In the study group , a catheter enters into the common femoral artery through a small incision on the skin of the groin and is placed in the distal of uterine artery where the artery is became transverse and the right and left uterine arteries are catheterized selectively and embolic material is injected into these arteries, which leads to arteries blockage. Then, the catheter is removed after 60 minutes and the site is packed for 6 hours

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr.Mojgan Ayazi

Street address

Emam Reza Hospital,Razi Boulevard,Sorkhleje

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Nasrin Jalilian

Position

Special of Obstetrics and Gynecology

Other areas of specialty/work

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Emam Reza Hospital,Razi Boulevard,Sorkhleje

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njalilian@kums.ac.irnjalilian@yahoo.com

Web page address

Person responsible for updating data

Contact

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