

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparison of anti-Mullerian hormone level in two treatment methods, myomectomy and uterine artery embolization, in patients with uterine fibroids

#### Protocol summary

##### Summary

The purpose of this study is investigating the anti-Mullerian hormone level in two treatment methods, myomectomy and uterine artery embolization, in patients with uterine fibroids. 50 women with fibroid problems referred to Imam Reza Hospital will be selected through available method and divided in two groups by choosing their type of treatment (Uterine artery embolization and myomectomy). Each patient is screened for anti Mullerian hormone level before operation. Patients are categorized in four age groups 20-25 and 25-30 and 30-35 and 35-40 and they are adjusted by age at two treatment methods. Pain on the third day, early occurred complications and the numbers of hospitalization days are recorded before discharge. Then each two weeks after operation, complications such as severe pain, hematoma, fever, infection, urinary problems and bleeding will be evaluated and anti-Mullerian hormone and hemoglobin levels will be checked 6 months after surgery. Inclusion criteria: age 25-40 years; having debilitating complaints such as severe bleeding due to myoma, uterine enlargement up to 16 weeks pregnancy, anemia and pressure on the pelvic organs of patients which candidates her for myomectomy. Exclusion criteria: probability of pelvic malignancies, ovarian pathologies, pelvic infections; desiring fertility, contrast sensitivity, renal disorders, and systemic autoimmune disorders.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014020114333N17**

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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### 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

Comparison of anti-Mullerian hormone level in two treatment methods, myomectomy and uterine artery embolization, in patients with uterine fibroids

##### Public title

Anti-Mullerian hormone levels of uterine artery

embolization in the treatment of patients suffering  
Myomectomy and uterine leiomyoma

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: age 25-40 years; having debilitating complaints such as severe bleeding due to myoma, uterine enlargement up to 16 weeks pregnancy, anemia and pressure on the pelvic organs of patients which candidates her for myomectomy. Exclusion criteria: probability of pelvic malignancies, ovarian pathologies, pelvic infections; desiring fertility, contrast sensitivity, renal disorders, and systemic autoimmune disorders.

### **Age**

From **25 years** old to **40 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **50**

### **Randomization (investigator's opinion)**

N/A

### **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**

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**

2013-09-11, 1392/06/20

#### **Ethics committee reference number**

31564/7/420/پ

## **Health conditions studied**

### 1

#### **Description of health condition studied**

urine fibroids and bleeding

#### **ICD-10 code**

N85.8

#### **ICD-10 code description**

Other specified noninflammatory disorders of uterus

## **Primary outcomes**

### 1

#### **Description**

Duration of returning to work

#### **Timepoint**

6 months after discharge

#### **Method of measurement**

Asking the patient

### 2

#### **Description**

anti-Mullerian hormone level

#### **Timepoint**

Baseline and 6 months after surgery

#### **Method of measurement**

Measurement in the laboratory

### 3

#### **Description**

Patients' complaints (hot flush, bleeding, pelvic pain and  
pressure, urinary problems, etc.)

#### **Timepoint**

6 months after intervention

#### **Method of measurement**

Asking the patient

### 4

#### **Description**

Pain level

#### **Timepoint**

One week after intervention

#### **Method of measurement**

Asking the patient

### 5

#### **Description**

Duration of hospitalization

#### **Timepoint**

Discharge date

#### **Method of measurement**

Based on patient records

### 6

#### **Description**

Cost of treatment

#### **Timepoint**

Discharge date

**Method of measurement**

Based on patient records

**Secondary outcomes**

empty

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

In the second treatment group, patients will be treated through myomectomy. Then anti-Mullerian hormone and hemoglobin levels will be checked 6 months after surgery.

**Category**

Treatment - Surgery

**2****Description**

In the first treatment group, patients will be treated through uterine artery embolization. Then anti-Mullerian hormone and hemoglobin levels will be checked 6 months after surgery.

**Category**

Treatment - Surgery

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

Emam Reza Hospital

**Full name of responsible person**

Dr.Afsaneh Mansouri

**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.farahnaz Keshavrzi

**Position**

Special of Obstetrics and Gynecology

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

Emam Reza Hospital,Razi Boulevard,Sorkhleje

**City**

Kermanshah

**Postal code****Phone**

+98 83 1427 6309

**Fax****Email**

fnkeshavarzi@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*