

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 2026

### A comparative study of ovarian reserve after uterine artery embolization and hysterectomy for uterine fibroma

#### Protocol summary

##### Summary

propose: To estimate ovarian reserve after uterine artery embolization and hysterectomy in uterine fibroma treatment. study design: RCT Inclusion criteria: age 25-45, sever vaginal bleeding , and pressure effect on pelvic organs. exclusion criteria: pelvic malignancy, substance media sensitivity. sample size: 66 cases Population: women who refer to hospital clinic. Intervention: determinant FSH levels before and after uterine artery embolization and hysterectomy Primary outcome: The same serum FSH levels before and after embolization Time: 20/2/2012 to 20/2/2014

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201202163461N5**  
Registration date: **2012-05-05, 1391/02/16**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-05-05, 1391/02/16

##### Registrant information

###### Name

Firoozeh Veisi

###### Name of organization / entity

Kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1823 4276

###### Email address

f\_veisi@kums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Kermanshah University of Medical Sciences

##### Expected recruitment start date

2012-02-20, 1390/12/01

##### Expected recruitment end date

2014-02-20, 1392/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study of ovarian reserve after uterine artery embolization and hysterectomy for uterine fibroma

##### Public title

The evaluation of ovarian reserve after uterine artery embolization

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age 25-45, sever vaginal bleeding , 16 week mass, anemia and pressure effect caused by uterine fibroma. exclusion criteria: pelvic malignancy, ovarian pathology, pelvic infection, substance media sensitivity.

##### Age

From **25 years** old to **45 years** old

##### Gender

Female

##### Phase

N/A

##### Groups that have been masked

No information

##### Sample size

Target sample size: **66**

**Randomization (investigator's opinion)**

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**

Kermanshah University of Medial Sciences

**Street address**

Kermanshah, Daneshgah Blv, Parastar Av

**City**

Kermanshah

**Postal code****Approval date**

2012-02-28, 1390/12/09

**Ethics committee reference number**

7/420/62088/پ

**Health conditions studied****1****Description of health condition studied**

uterine fibroma and bleeding

**ICD-10 code**

N85.8

**ICD-10 code description**

فیبرومهای اکتسابی رحم

**Primary outcomes****1****Description**

FSH level

**Timepoint**

Third day of month before and third day six month after both procedures

**Method of measurement**

serum level , mIU/ cc

**Secondary outcomes****1****Description**

Number of dominant follicle between 12-14 days of cycle

**Timepoint**

Before and 6 month after intervention

**Method of measurement**

One dominant follicle by sonography

**2****Description**

Hb level

**Timepoint**

Before and 6 month after intervention

**Method of measurement**

Blood level

**3****Description**

Duration of hospitalization

**Timepoint**

hospitalization time

**Method of measurement**

The number of days hospitalization through intervention

**4****Description**

Time required to return normal activity

**Timepoint**

The number of weeks to return normal activity

**Method of measurement**

weeks

**5****Description**

Pain level after intervention

**Timepoint**

one week after intervention

**Method of measurement**

1-10 score

**6****Description**

Cost of procedure

**Timepoint**

cost of hospitalization and

**Method of measurement**

Rials

**7****Description**

Repeat intervention

**Timepoint**

By 6 month after first intervention

**Method of measurement**

Operation and hormonal drugs

**8****Description**

Patients symptoms

**Timepoint**

6 month after intervention

**Method of measurement**

Hot flash, bleeding,pain,...

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

Embolization: Record of patient demographic data . The evaluation of FSH level in third day of cycle before intervention. The evaluation of Hb level before intervention. The evaluation of FSH and Hb 6 months after intervention. The evaluation of ovarian follicle before and 6 months after intervention.

**Category**

Treatment - Surgery

**2****Description**

Hysterectomy: Record of patient demographic data . The evaluation of FSH level in third day of cycle before intervention. The evaluation of Hb level before intervention. The evaluation of FSH and Hb 6 months after intervention. The evaluation of ovarian follicle before and 6 months after intervention.

**Category**

Treatment - Surgery

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

Imam Reza Hospital

**Full name of responsible person**

firoozeh veisi

**Street address**

Kermanshah, Daneshgah blv,Parastar av.

**City**

Kermanshah

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

Kermanshah University of Medical Sciences

**Full name of responsible person**

firoozeh veisi

**Street address**

Kermanshah,Daneshgah Blvd.Parastar  
AV.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****Name of organization / entity**

Kermanshah University of Medical Sciences,Kermanshah,Iran

**Full name of responsible person**

firoozeh veisi

**Position**

Assistant professor,faculty member

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

Kermanshah ,Daneshgah blv,Parastar av.Kermanshah  
University of Medical Sciences

**City**

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**Full name of responsible person**

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**Position**

Assistant professor ,faculty member

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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical  
Sciences, kermanshah, Iran

**Full name of responsible person**

firoozeh veisi

**Position**

**Other areas of specialty/work**

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**Phone**

+98 83 1427 6309

**Fax**

## 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*