

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)

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+98 83 1823 4276

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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 Medical 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

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Kermanshah,Daneshgah Blvd.Parastar
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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**

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Position

Assistant professor ,faculty member

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

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Sciences, kermanshah, Iran

Full name of responsible person

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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