Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Iran (Islamic Republic of)
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+98 83 1821 4653
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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

utrine 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
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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