Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of uterine artery embolization on fertility

Protocol summary

Study aim
Determine the fertility rate following the uterine artery embolization

Design
In this clinical trial study, 60 patients with uterine fibroid will be separated into two groups. interventional group will be treated with uterine artery embolization and control group will be treated with myomectomy.

Settings and conduct
this prospective study will be done in the Radiology ward at Firoozgar hospital in partnership with the maternity ward. All patients with the diagnosis of fibroid that will be treated with uterine artery embolization will be included. patients answer the questionnaire for uterine fibroid sign and symptoms. after the intervention, CBC, CRP, Duration of returning to work, Early complications, infections, PTE and hysterectomy will be checked. All patients will be followed 6 months after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: smaller than 40 years old, Intending to get pregnant sonography explain myoma in uterine larger than 4cm in the largest diameter, the serum level of FSH lower than 30 IU/L in the third day of period. Exclusion criteria: peduncular fibroid with thin pedicle, fibroid bigger than uterine in 24 weeks of pregnancy, intracavity part of fibroid larger than 3cm, virgin patient want to get married.

Intervention groups
In this study interventional group will be treated with uterine artery embolization. Control group will be treated with myomectomy.

Main outcome variables
LH, FSH and Estradiol(third day of period), the sign of uterine fibroid questionnaire, CBC, CRP and CA-125(tumor marker), Duration of returning to work.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170925036388N2**
Registration date: **2018-02-23, 1396/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-23, 1396/12/04**
Update count: **0**

Registration date
2018-02-23, 1396/12/04

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6606 9049

Email address
rajabzadeh.a@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-06-22, 1396/04/01

Expected recruitment end date
2019-07-22, 1398/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of uterine artery embolization on fertility

Public title
Evaluating the effect of uterine artery embolization on fertility

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Smaller than 40 years old Intending to get pregnant Sonography explain myoma in uterine larger than 4cm in the largest diameter (biggest one larger than 4cm, for more than one myoma) Serum level of FSH lower than 30 IU/L in third day of period

Exclusion criteria:

Peduncular fibroid with thin pedicle that is smaller than 50% of fibroid apex. Fibroid bigger than uterine in 24 weeks of pregnancy Intracavity part of fibroid larger than 3cm Virgin patient want to get married (except patient with previous surgery)

Age

To **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not 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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.IUMS.FMB.IEC1396.9411282010

Health conditions studied

1

Description of health condition studied

uterine fibroid

ICD-10 code

D25.9

ICD-10 code description

Leiomyoma of uterus, unspecified

Primary outcomes

1

Description

LH, FSH and Estradiol(third day of period)

Timepoint

Baseline and 6 months after surgery

Method of measurement

Blood sampling

2

Description

Sign of uterine fibroid questionnaire

Timepoint

Baseline and 6 months after surgery

Method of measurement

Questionnaire

3

Description

CBC

Timepoint

Baseline and 6 months after surgery

Method of measurement

Blood sampling

4

Description

Duration of returning to work

Timepoint

6 months after surgery

Method of measurement

Asking the patient

5

Description

CRP

Timepoint

Baseline and 6 months after surgery

Method of measurement

Blood sampling

6

Description

CA-125(tumor marker)

Timepoint

Baseline and 6 months after surgery

Method of measurement

Blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will be treated with uterine artery embolization. Then LH, FSH, Estradiol and CA-125(tumor marker) will be checked 6 months after surgery.

Category

Treatment - Surgery

2

Description

Control group: Patients will be treated with myomectomy.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Dr. Alale Rajabzade Kanafi

Street address

Firoozgar hospital, Behafarin St., Karim kan Ave., Valiasr Sq., Tehran

City

Tehran

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1593747811

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h_firoozgar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Mohamad Reza Babaei

Street address

Interventional sonography room, Firoozgar hospital, Beh Afarin street, Karim Khan Ave., Valiasr Sq.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Dr. Mohamad Reza babaei

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Alale Rajabzade Kanafi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Radiology

Street address

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Email
rajabzadeh.a@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All information used for this research can be shared after unidentifying the identity of patients.
When the data will become available and for how long
Starting access after accepting by a valid scientific journal and publishing it
To whom data/document is available
For academic researchers and in the field of science
Under which criteria data/document could be used
All researchers can use all published material and if all or part of this research is published by other people, the name and source of this research and its researchers should be mentioned.
From where data/document is obtainable
Dr. Alale Rajabzade Email: rajabzadeh.a@iums.ac.ir
What processes are involved for a request to access data/document
The applicant can request the type of files by email.
Comments