

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Mechanical effect of uterine artery ligation on ovarian reserve during myomectomy laparotomy

#### Protocol summary

##### Study aim

Determining the mechanical effect of Uterine artery ligation on ovarian reserve during myomectomy laparotomy

##### Design

The study is before and after, without blinding, with a sample size of 32

##### Settings and conduct

All initial patient information, including age, initial BMI, AMH and after 3 months of operation, the size of the myoma in ultrasound, the menstrual pattern, and the history of abdominal surgery, will be collected in the form of data collection that will be adjusted for this purpose. Information required from A complete initial biography that will be taken from each individual patient will be provided as well as birth certificate information, patient's medical history, surgery descriptions, laboratory data. All of this information is included in the pre-prepared review form that is attached, will be completed for each subject.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: Infertility in a person with ovarian factor No PCO Not having endometriosis (BMI <30) Regular menstrual pattern Having informed consent to enter the study Exclude criteria: Dissatisfaction with entering the study People who the specialist discovers that treatment can be at risk for them. A person who is likely to be unavailable at a later date for subsequent tests.

##### Intervention groups

Intervention group: open myomectomy surgery (laparotomy)

##### Main outcome variables

AMH after 3 months,

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20150817023666N10**

Registration date: **2018-02-17, 1396/11/28**

Registration timing: **prospective**

Last update: **2018-02-17, 1396/11/28**

Update count: **0**

#### Registration date

2018-02-17, 1396/11/28

#### Registrant information

##### Name

Abolfazl Mehdizadeh kashi

##### Name of organization / entity

Iran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 216651500

##### Email address

mehdizadeh.a@iums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-02-20, 1396/12/01

#### Expected recruitment end date

2020-02-20, 1398/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Mechanical effect of uterine artery ligation on ovarian reserve during myomectomy laparotomy

**Public title**

Effect of tourniquet ligation on ovarian reserve

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Infertility in person with ovarian factor No PCO No endometriosis (BMI <30) Regular menstrual pattern informed consent to enter the study

**Exclusion criteria:**

Dissatisfaction to enter the study The person the practitioner determines that treatment can be at risk for them A person who is likely to be unavailable at a later date for subsequent tests

**Age**

No age limit

**Gender**

Female

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: 32

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**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**

Rasoul-e-Akram Hospital, Mazar-i-Mansouri St., Sattarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Approval date**

2018-01-24, 1396/11/04

**Ethics committee reference number**

IR.IUMS.REC 1394.25946

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

Leiomyoma of uterus

**ICD-10 code**

D25

**ICD-10 code description**

Leiomyoma of uterus

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

AMH serum level measurement

**Timepoint**

Measurement of baseline serum level and 3 months later

**Method of measurement**

Blood sampling

**Secondary outcomes**

empty

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

Intervention group: uterine artery ligation

**Category**

Treatment - Surgery

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

Hazrat-e Rasoul-e- Akram Hospital

**Full name of responsible person**

Abolfazl mehdizadeh-kashi

**Street address**

Rasoul-e-Akram Hospital, Mazar-i-Mansouri St., Sattarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6650 9283

**Fax**

+98 21 6435 2680

**Email**

amehdizadehkashi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyed Kazem Malakouti

**Street address**

Hemat Highway next to Milad Tower, Iran University of Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8670 2503

**Fax**

+98 21 6435 2680

**Email**

PR@iums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Abolfazl Mehdizadeh-kashi

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Rasoul-e-Akram Hospital, Mazar-i-Mansouri St., Sattarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6650 9283

**Fax**

+98 21 6435 2680

**Email**

amehdizadehkashi@yahoo.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Samaneh Rokhgireh

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Rasoul-e-Akram Hospital, Mazar-i-Mansouri St., Sattarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6650 9283

**Fax**

+98 21 6435 2680

**Email**

s.rokhgireh@gmail.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Samaneh Rokhgireh

**Position**

Assistant profesor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Rasoul-e-Akram Hospital, Mazar-i-Mansouri St., Sattarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6650 9283

**Fax**

+98 21 6435 2680

**Email**

s.rokhgireh@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available