

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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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

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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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Samaneh Rokhgireh

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Samaneh Rokhgireh

Position

Assistant profesor

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Gynecology and Obstetrics

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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