

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Investigating the effect of temporary and permanent uterine artery ligation(UAL) on ovarian reserve in laparoscopic myomectomy patients.

#### Protocol summary

##### Study aim

Evaluation of the effect of temporary and permanent uterine artery ligation to control bleeding on ovarian reserve using anti-Mullerian hormone (AMH) measurement in laparoscopy.

##### Design

A clinical trial with a control group and two intervention groups on 54 patients and study type is parallel.

##### Settings and conduct

The study population included patients undergoing laparoscopic myomectomy in the age range of 18 to 45 years who referred to Shahid Beheshti Hospital in 2023. Patients are sub divided in 3 groups. The first group has an inappropriate location of the uterine artery and the second one has patients who want to preserve the uterus but do not want to become pregnant who are in the permanent group and the third group are patients who have infertility and are planning to become pregnant in the future.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include age between 18 and 45 years old who have a maximum of 3 myoma and less than 10 cm or symptomatic myomas. Exclusion criteria: History of receiving hormonal therapy or history of previous surgery on the ovary.

##### Intervention groups

In the intervention group, before myomectomy to control the bleeding of the uterine artery from the beginning of separation from the hypogastric artery is temporarily or permanently closed and in the control group vasopressin is injected in the myoma capsule to control the bleeding.

##### Main outcome variables

Checking the ovarian reserve after the operation and checking the amount of bleeding during the operation

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230519058228N2**

Registration date: **2023-08-17, 1402/05/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-08-17, 1402/05/26**

Update count: **0**

#### Registration date

2023-08-17, 1402/05/26

#### Registrant information

##### Name

Maryam Hashemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3668 7860

##### Email address

maryam.hashemi@med.mui.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-07-23, 1402/05/01

#### Expected recruitment end date

2023-12-21, 1402/09/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Investigating the effect of temporary and permanent uterine artery ligation(UAL) on ovarian reserve in laparoscopic myomectomy patients.

## Public title

The effect of uterine artery ligation on fertility

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Women between 18 and 45 years old Patients with up to 3 myomas Myomas smaller than 10 cm Patients with symptomatic myomas

### Exclusion criteria:

History of receiving hormone therapy History of previous surgery on the ovary

## Age

From **18 years** old to **45 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **54**

## 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 Isfahan University of Medical Sciences

##### Street address

Isfahan, Hezar Jerib St ,Isfahan University of Medical Sciences

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2023-07-03, 1402/04/12

#### Ethics committee reference number

IR.MUI.MED.REC.1402.140

## Health conditions studied

### 1

#### Description of health condition studied

Uterine myoma

#### ICD-10 code

D25.9

#### ICD-10 code description

Leiomyoma of uterus, Unspecified

## Primary outcomes

### 1

#### Description

Evaluation of ovarian reserve (AMH) after laparoscopic myomectomy

#### Timepoint

Before and 3 months after the operation

#### Method of measurement

Taking a blood sample from the patient

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: In women with uterine myoma who have indications for laparoscopy, before starting myomectomy to control bleeding, the uterine artery is temporarily closed and the amount of bleeding will be recorded at the end of the procedure. Patients' tests are reviewed before and 3 months after the study.

#### Category

Treatment - Surgery

### 2

#### Description

Intervention group 2: In women with uterine myoma who have indications for laparoscopy, before starting myomectomy to control bleeding, the uterine artery is permanent closed and the amount of bleeding will be recorded at the end of the procedure. Patients' tests are reviewed before and 3 months after the study.

#### Category

Treatment - Surgery

### 3

#### Description

Control group: In women with uterine myoma who have indications for laparoscopy, vasopressin injection will be used to control bleeding before starting myomectomy, and the amount of bleeding will be recorded at the end of the procedure. Patients' tests are reviewed before and 3 months after the study.

**Category**

Treatment - Drugs

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

Shahid Beheshti Hospital of Isfahan city

**Full name of responsible person**

Maryam Hashemi

**Street address**Shahid Beheshti Hospital, Shahid Motahhari street  
, Isfahan**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

maryam.hashemi@med.mui.ac.ir

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Gholam Reza Asgari

**Street address**Esfahan University of Medical Science, Hezar Jerib  
Street.**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3668 8138

**Email**

askari@mui.ac.ir

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam Hashemi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Isfahan, Hezar Jerib St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3775 4892

**Email**

maryam.hashemi@med.mui.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam Hashemi

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Assistant Professor

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**Sharing plan**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The data will not be shared separately, but the results of their analysis will be shared in the article

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available