

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)

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Email address

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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

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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 centers1**Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital of Isfahan city

Full name of responsible person

Maryam Hashemi

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Gholam Reza Asgari

Street addressEsfahan University of Medical Science, Hezar Jerib
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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

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

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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