

# Assessment of bleeding reduction technique in laparoscopic myomectomy (keyhole surgery to remove fibroids)

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<b>Registration date</b> 22/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/04/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of this study is to determine whether patients who underwent laparoscopic fibroid removal and temporary placement of a metallic mechanism (called a "clip"), which acts as a clamp on the uterine arteries and utero-ovarian ligaments, have decreased bleeding during surgery, compared to patients who underwent laparoscopic myomectomy without said clips.

### Who can participate?

Patients with uterine fibroids requiring surgical treatment via laparoscopy and with a desire to preserve the uterus.

### What does the study involve?

This is a study in which patients who underwent laparoscopic myomectomy with temporary placement of "clips" in the uterine arteries and utero-ovarian ligaments, which are removed at the end of the intervention, are compared with another control group of patients who underwent laparoscopic myomectomy with the traditional technique (without "clips") usually performed in other centers.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

University Hospital Ramon y Cajal (Spain)

### When is the study starting and how long is it expected to run for?

January 2020 to December 2022

### Who is funding the study?

University Hospital Ramon y Cajal (Spain)

Who is the main contact?

Dr Enrique Moratalla Bartolome, [enrique.moratalla@salud.madrid.org](mailto:enrique.moratalla@salud.madrid.org)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Enrique Moratalla Bartolome

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

NCT05994560

### Protocol serial number

324-19

## Study information

### Scientific Title

Value of temporary occlusion of the uterine arteries in laparoscopy myomectomy

### Study objectives

The objective of this study is to determine whether patients undergoing laparoscopic myomectomy with temporary occlusion of the uterine arteries and utero-ovarian ligaments using clips experience a decrease in blood loss during surgery compared to patients who undergo laparoscopic myomectomy without clips.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

1. approved 24/02/2020, Medicine Research Ethics Committee University Hospital Ramon y Cajal (M-607, 9, 100, Madrid, 28034, Spain; +34 913368322; ceic.hrc@salud.madrid.org), ref: 324-19

2. approved 12/02/2020, MEDICINE RESEARCH ETHICS COMMITTEE HM HOSPITALS (Avda. Montepríncipe, 25., Boadilla del Monte, 28660, Spain; -; secretariaceic@hmhospitales.com), ref: 20.01.1492-GHM

## **Study design**

Longitudinal prospective randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Laparoscopic myomectomy with temporary occlusion of the uterine arteries and utero-ovarian ligaments

## **Interventions**

Patients who underwent laparoscopic myomectomy with temporary occlusion of the uterine arteries and utero-ovarian ligaments using clips will be analyzed with a control group of patients who underwent laparoscopic myomectomy with the traditional technique (surgery without temporary occlusion of uterine arteries).

Patients with symptomatic fibroids who require surgery to treat them, from the Gynecology Service of the Ramón y Cajal Hospital and HM Hospitals. Patients will be randomized into 2 groups: exposed (patients with temporary occlusion of the uterine arteries by clips during surgery) and non-exposed (patients without temporary occlusion of the uterine arteries during surgery).

A patient will be recruited in the pre-surgical consultation when laparoscopic myomectomy is indicated, randomizing both groups by simple random sampling. An informed consent will be delivered to the patients, who have to accept and sign in order to participate in the study. The diagnosis of the presence of fibroids will be made by abdominal and/or transvaginal gynecological ultrasound and/or nuclear magnetic resonance. Fibroids will be quantified, measured and their location described.

The patients included in the study will have their pre-surgical hemoglobin determined by preoperative analysis and another post-surgical hemoglobin sample will be determined the day after surgery. The need for transfusion, blood loss during surgery (aspirate the blood content), surgical time, hospital stay, symptom improvement and complications will be assessed. In addition, clinical data on the patients will be collected: age, height, weight, race, concomitant diseases and treatment, family history, age at menarche, tobacco and alcohol consumption, main clinic where the surgery is performed.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Blood loss (by assessing pre- and postoperative hemoglobin in g/dL and intraoperative blood aspirate in milliliters) measured using the amount of aspirated fluid at the end of the procedure minus the amount of fluid used for irrigation in ml.

### **Key secondary outcome(s)**

Measured using patient records unless noted:

1. Surgical time (minutes)
2. Need for transfusion (yes/no)
3. Length of hospital stay (days)
4. Preoperative hemoglobin (g/dl) was obtained within 24 hours before surgery, and postoperative hemoglobin was collected on postoperative day 1
5. Surgical complications were documented

### **Completion date**

31/12/2022

## **Eligibility**

### **Key inclusion criteria**

Patients with uterine fibroids requiring surgical treatment via laparoscopy and with a desire to preserve the uterus.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

50 years

### **Sex**

Female

### **Total final enrolment**

80

### **Key exclusion criteria**

1. Patients who do not meet the inclusion criteria.
2. Women with symptomatic fibroids who are not candidates for laparoscopic surgery and/or have no desire to preserve the uterus.
3. Patients for whom technical placement of clips during the intervention is not possible.

**Date of first enrolment**

12/02/2020

**Date of final enrolment**

21/12/2022

## Locations

**Countries of recruitment**

Spain

**Study participating centre****University Hospital HM Monteprincipe**

Avenida de Montepríncipe nº 25

Boadilla del Monte

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**Study participating centre****University Hospital Ramon y Cajal**

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**Study participating centre****University Hospital HM Sanchinarro**

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Madrid

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## Sponsor information

**Organisation**

Hospital Universitario Ramón y Cajal

**ROR**

<https://ror.org/050eq1942>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Hospital Universitario Ramon y Cajal

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr. Enrique Moratalla, emoratallab@gmail.com

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		25/03/2024	09/04/2024	Yes	No
<a href="#">Participant information sheet</a>	version 2		22/11/2023	No	Yes