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

Submission date	Recruitment status No longer recruiting	 Prospectively registered 		
11/11/2023		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/11/2023	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
09/04/2024	Surgery			

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)

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

NCT05994560

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See outputs table

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 measure

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.

Secondary outcome measures

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

Overall study start date

11/01/2020

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

Female

Target number of participants

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 Spain 28660

Study participating centre University Hospital Ramon y Cajal

M-607, 9, 100, Madrid Spain 28034

Study participating centre University Hospital HM Sanchinarro

Calle Oña 10 Madrid Spain 28050

Sponsor information

Organisation

Hospital Universitario Ramón y Cajal

Sponsor details

M-607, 9, 100, Madrid Spain 28034 +34 913368000 ceic.hrc@salud.madrid.org

Sponsor type

Hospital/treatment centre

Website

https://www.comunidad.madrid/hospital/ramonycajal/

ROR

https://ror.org/050eq1942

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital Universitario Ramon y Cajal

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2023

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 version 2	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			22/11/2023	No	Yes
Results article		25/03/2024	09/04/2024	Yes	No