ISRCTN89994856 https://doi.org/10.1186/ISRCTN89994856

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

Submission date
11/11/2023

Recruitment status
No longer recruiting

Registration date
22/11/2023

Overall study status
Completed

Last Edited
09/04/2024

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Enrique Moratalla Bartolome

ORCID ID
https://orcid.org/0000-0002-2653-2043

Contact details
M-607, 9, 100,
Madrid
Spain
28034
+34 913368105
enrique.moratalla@salud.madrid.org

Additional identifiers

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

Primary study design
Interventional

Study design
Longitudinal prospective randomized controlled trial

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
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

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?
Results article		25/03/2024	09/04/2024	Yes	No
Participant information sheet	version 2		22/11/2023	No	Yes