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Temporary occlusion of the hypogastric artery to reduce blood loss associated with laparoscopic myomectomy

Submission date
27/06/2023

Recruitment status
No longer recruiting

Registration date
03/07/2023

Overall study status
Completed

Last Edited
07/09/2023

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Uterine leiomyomas, or uterine fibroids, are benign tumors in the pelvic region that are commonly found in women. For women of reproductive age experiencing symptoms from these tumors, laparoscopic myomectomy (LM) is the preferred treatment option in which myomas are surgically removed through small incisions in the abdomen. In this study, the authors propose that combining LM with blocking blood flow of arteries in the pelvis, or temporary occlusion of the hypogastric artery (TOHA) using vascular clips, can reduce uterine blood flow during surgery and effectively decrease surgery-related blood loss.

Who can participate?
Adult women aged 18-49 years old diagnosed with intramural uterine leiomyomas larger than 4 cm in diameter, who preferred LM and wished to preserve fertility.

What does the study involve?
Participants were randomized into two parallel groups:
1. Patients undergoing standard LM
2. Patients undergoing LM with TOHA clipping.

What are the possible benefits and risks of participating?
The main benefits regard reduced surgery-associated blood loss. There are no foreseen risks associated with the intervention.

Where is the study run from?
Ob-Gyn Clinic of Emergency Municipal Clinical Hospital in Timisoara, Romania. The clinic is affiliated with "Victor Babes" University of Medicine and Pharmacy, Timisoara, Romania.

When is the study starting and how long is it expected to run for?
January 2018 to December 2021

Who is funding the study?
"Victor Babes" University of Medicine and Pharmacy, Timisoara, Romania

Who is the main contact?
Prof Laurentiu Pirtea (Principal investigator), pirtea.laurentiu@umft.ro
Dr Cristina Secosan, secosan.cristina@umft.ro

Contact information

Type(s)
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Additional identifiers

Study information

Scientific Title
Investigation of bilateral Temporary Occlusion of the Hypogastric Artery in women undergoing laparoscopic myomectomy to minimize consequences of blood loss

Acronym
TOHAs

Study objectives
Combining laparoscopic myomectomy with a bilateral temporary occlusion of the hypogastric artery (TOHA) using vascular clips minimizes uterine blood flow during surgery and can significantly reduce surgery-associated blood loss.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/12/2018, Human Ethical Committee of “Victor Babes” University of Medicine and Pharmacy (Piata Eftimie Murgu 2, Timisoara, 300041, Romania; +40 256466001; cecs@umft.ro), ref: 44/10.12.2018

Study design
Proof-of-concept single-center interventional single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Laparoscopic myomectomy in adult women

Interventions

Combining laparoscopic myomectomy with temporary bilateral occlusion of the hypogastric artery.

Study arms:
There are two arms that include participants who are randomly allocated to the following interventions:
LM – laparoscopic myomectomy with no hypogastric artery clipping
LM + TOHA – laparoscopic myomectomy with temporary occlusion of the hypogastric artery

Method of randomization:
Randomization was single-blind and performed with the R package "blockrand" version 1.5.

Intervention providers:
All surgical procedures are performed by a single and highly proficient surgeon with over a decade of experience in laparoscopic surgery.

Modes of delivery
Prior to the surgery, neither Gonadotropin-Releasing Hormone (GnRH) agonists nor any intra-operative hemostatic drugs, such as vasopressin injections, are employed. Before initiating surgical procedures, general anesthesia was induced concomitantly with orotracheal intubation. Abdominal access was obtained via a direct trocar entry technique. CO2 insufflation was used to create a pneumoperitoneum with a low intra-abdominal pressure of up to 12 mmHg. A 10 mm trocar was positioned on the median line, 8 cm away from the umbilicus, while two 5 mm trocars are situated on each side of the lower abdomen. The patient was then reclined in a Trendelenburg position. The parietal peritoneum was incised below the lumbo-ovarian ligament. The ureter and anterior trunk of the hypogastric artery are identified in the area where these two structures run parallel. The ureter and hypogastric artery are identified using blunt dissection. A metallic clip was then placed on the anterior trunk of the hypogastric artery, cranially to the uterine artery emergence.

The uterine wall was incised, and the myoma/s are located and then removed using traction and countertraction maneuvers. Next, in-bag morcellation was used to remove the leiomyoma/s. The uterine wall was sutured with a double-layer stitch, utilizing a 29 mm, 3/8 circle needle, and Vicryl 2.0 thread. Once the uterine wall had been closed, hemostatic clips are gently removed by traction using atraumatic Johan fenestrated forceps.

Location where the intervention occurred
All surgical interventions are performed within the facilities of the Ob-Gyn Clinic of Emergency Municipal Clinical Hospital in Timisoara, Romania. The clinic is a tertiary referral hospital and is affiliated with "Victor Babes" University of Medicine and Pharmacy, Timisoara, Romania.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Total hemoglobin concentration (g/dL) measured using a blood gas analyzer system (carried out in the CO-oximetry module) within the hospital laboratory before and immediately after the surgery

Key secondary outcome(s))

1. Required iron perfusion measured using the quantity of iron administered by intravenous infusion after surgery decided by the consultant based on ferritin concentration < 100 µg.l-1 after surgery
2. Required postoperative blood transfusion measured using blood testing and determined by the consultant based on a hemoglobin level of 70-80 g.l-1 measured after surgery
3. Anemia measured using blood testing and diagnosed based on hemoglobin less than 120 g/L (12 g/dL) as a dichotomous variable after surgery
4. Overall operative time measured using medical records as the time elapsed from the initial incision to final skin closure after surgery
5. Twelve-month post-operative spontaneous pregnancy measured using medical records as any pregnancy recorded within 12 months after laparoscopic myomectomy, without assisted reproductive measures at one timepoint at the end of the study
6. Hospital re-admission rate of participants in the trial who return to the hospital within seven days of discharge after laparoscopic myomectomy measured using medical records at one timepoint at the end of the study
7. Reports of death, including in-hospital death, or within 14 days of discharge after laparoscopic myomectomy, measured using medical records at one timepoint at the end of the study

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Aged between 18 and 49 years old
2. Preference for laparoscopic myomectomy and their desire to preserve fertility
3. Intramural uterine leiomyomas greater than 4 cm in diameter

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
49 years

Sex
Female

Total final enrolment
60

Key exclusion criteria
1. Patients who did not agree to the enrollment or did not pass inclusion criteria (such as: age over 50, no preference for fertility preservation, personal option for hysterectomy)
2. Other types of myomas (such as submucosal or sub-serosal location), or intramural myomas under 4 cm which did not have an impact on the uterine cavity
3. Suspected of malignancy

Date of first enrolment
01/01/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Romania

Study participating centre
Emergency Municipal Clinical Hospital
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Sponsor information

Organisation
Victor Babeș University of Medicine and Pharmacy Timișoara

ROR
https://ror.org/00afdp487

Funder(s)

Funder type
University/education

Funder Name
Victor Babeș University of Medicine and Pharmacy Timișoara

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated during this study will be made available upon institutional contact and reasonable request from Dr Cristina Secosan, secosan.cristina@umft.ro. These datasets will include individual patient data meta-analysis (IPD meta-analysis).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/08/2023	07/09/2023	Yes	No
Participant information sheet	Informed consent [English]		03/07/2023	No	Yes
Participant information sheet	Informed consent [Romanian]		03/07/2023	No	Yes
Statistical Analysis Plan			03/07/2023	No	No