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Ovarian function after the use of various hemostatic techniques during treatment for endometrioma

Submission date
17/12/2017

Recruitment status
No longer recruiting

Registration date
18/12/2017

Overall study status
Completed

Last Edited
08/12/2020

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Introduction: Endometriosis is defined by the presence of endometrial tissue outside the uterine cavity due to causes not yet fully elucidated. The disease affects approximately 2% of women of reproductive age and is associated with infertility. Approximately 17% to 44% of women with endometriosis exhibit endometrioma, or ovarian endometriosis. Laparoscopic cystectomy is currently considered the gold standard treatment for this problem, resulting in improvement of symptoms, a lower recurrence rate and a higher pregnancy rate among infertile patients. However, several studies have shown that this treatment is not free from risks because it is associated with reduction of the ovarian reserve due to accidental removal of ovarian cortex during stripping of the capsule or damage caused by the coagulation energy during hemostasis, even when performed by experienced surgeons. There is still controversy in the literature as to the cause of the reduction of the ovarian reserve, as the mere presence of endometrioma reduces ovarian function by itself.
Aim: To compare the effects of different hemostatic methods on the ovarian function of women subjected to laparoscopic surgery for ovarian endometrioma.
Methods: Open-label randomized clinical trial to be conducted at Lauro Wanderley University Hospital from September 2017 to August 2020. Eighty-four patients will be randomly allocated to three groups according to the hemostatic technique used during laparoscopic surgery for ovarian endometrioma: bipolar coagulation, laparoscopic suture and hemostatic matrix. Ovarian function will be assessed by measuring serum anti-Mullerian hormone and follicle-stimulating hormone levels and by ultrasound antral follicle counts before surgery and 1, 3 and 6 months after surgery.

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
U1111-1203-2508

Study information

Scientific Title
Ovarian function after the use of various hemostatic techniques during treatment for endometrioma

Study objectives
Among patients with ovarian endometrioma subjected to laparoscopy surgery and randomized to receive hemostasis following stripping of the capsule through bipolar coagulation, suture or hemostatic agents:
1. Ovarian function is less damaged when a hemostatic matrix is used compared with suture and bipolar coagulation.
2. Ovarian function is less damaged when suture is performed compared with a hemostatic matrix and bipolar coagulation.
3. Ovarian function is less damaged when suture and a hemostatic matrix are used compared with bipolar coagulation.
4. There are no differences among the methods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee at the Medical Sciences Center, Federal University of Paraíba, Certificate of Presentation for Ethical Assessment (CAAE), ref: no. 71621717.9.0000.8069, www.plataformabrasil.saude.gov.br.

Study design
An open-label randomised clinical trial will be performed to compare the impact of hemostatic techniques (bipolar coagulation versus laparoscopic suture versus hemostatic matrix) during laparoscopic surgery for ovarian endometrioma on the ovarian follicular reserve.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Compare the impact of hemostatic techniques (bipolar coagulation versus laparoscopic suture versus hemostatic matrix) during laparoscopic surgery for ovarian endometrioma on the ovarian follicular reserve

Interventions
Hemostatic techniques (bipolar coagulation versus laparoscopic suture versus hemostatic matrix) during laparoscopic surgery for ovarian endometrioma.
The sample are divided into three groups according to the hemostatic technique used:
1. Bipolar coagulation (bipolar tweezers, Astus Medical ©, Copyright 2015, Tampa FL, USA) with 30 W power and a Valleylab generator (Medronic ©, Copyright 2017, Medtronic Parkway, Minneapolis, USA); the number of coagulated points will be counted, and the time for coagulation will be measured in seconds.
2. Laparoscopic suturing with simple suture (2-0/Vicryl polyglactin absorbable synthetic suture; Ethicon Inc., New Jersey, USA); the number of sutures are recorded.
3. Hemostatic matrix (Surgicel® Original Absorbable Hemostat, Ethicon, USA).

Intervention Type
Procedure/Surgery

Primary outcome measure
Anti-Mullerian hormone (AMH) measurement before surgery (1 month before surgery) and 1, 3 and 6 months after surgery

Secondary outcome measures
Follicle-stimulating hormone (FSH) FSH measurement before surgery (1 month before surgery) and 1, 3 and 6 months after surgery
Ultrasound antral follicle count before surgery (1 month before surgery) and 1, 3 and 6 months after surgery

Overall study start date
01/09/2017

Completion date
30/08/2020

Eligibility

Key inclusion criteria
1. Age 18 to 40 years old
2. Regular menstrual cycle (21 to 35 days)
3. Unilateral ovarian cyst suggestive of endometrioma, measuring 3 to 7 cm, on ultrasound
4. Endometrioma and indication of laparoscopic surgery for cyst removal due to pelvic pain, infertility or cyst persistence

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
86

Key exclusion criteria
1. Previous ovarian surgery
2. Endocrine dysfunction (diabetes, thyroid disorders, hyperprolactinemia, adrenal disease, polycystic ovary syndrome)
3. Use of hormones in the past 3 months
4. Suspected ovarian malignant tumor requiring oophorectomy
5. History of chemotherapy or radiotherapy
6. Coagulation disorders
7. Pregnancy
8. Autoimmune disease
9. Severe endometriosis

Date of first enrolment
05/02/2018

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
Brazil

Study participating centre

Lauro Wanderley University Hospital (HULW)
João Pessoa
Brazil
58033-455

Study participating centre
Santa Casa de Sao Paulo School of Medical Science
Sao Paulo
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01221-020

Sponsor information

Organisation
Santa Casa de Sao Paulo School of Medical Science

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01z6qpb13

Funder(s)

Funder type
Research organisation

Funder Name
Fundação de Amparo à Pesquisa do Estado de São Paulo

Alternative Name(s)
São Paulo Research Foundation, State of São Paulo Research Foundation, Foundation for Research Support of the State of São Paulo, FAPESP

Funding Body Type
Private sector organisation

Funding Body Subtype
Local government

Location
Brazil

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/07/2019	08/12/2020	Yes	No