







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

<b>Submission date</b> 17/12/2017	<b>Recruitment status</b> No longer recruiting	 Prospectively registered
		 Protocol added
<b>Registration date</b> 18/12/2017	<b>Overall study status</b> Completed	 SAP not yet added
		 Results not yet added and study completed for more than 2 years
<b>Last Edited</b> 08/12/2020	<b>Condition category</b> Pregnancy and Childbirth	 Raw data not yet added
		 Study completed

## Plain English Summary

**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

**Contact name**

Mrs Raquel Araújo

**Contact details**

Rua Do Sol, 100, Miramar

João Pessoa

Brazil

58043-330

+55 83 99305-9773

raquel.silveira@gmail.com

## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Protocol/serial number**

U1111-1203-2508

## **Study information**

**Scientific Title**

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

**Study hypothesis**

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](http://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**

#### **Condition**

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 (Medtronic ©, 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

**Overall study end date**

30/08/2020

## Eligibility

**Participant 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

**Participant 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

**Recruitment start date**

05/02/2018

**Recruitment end date**

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  
Brazil  
01221-020

## **Sponsor information**

**Organisation**  
Santa Casa de Sao Paulo School of Medical Science

**Sponsor details**  
R Dr Cesário Motta Jr, 61  
São Paulo  
Brazil  
01221-020  
+55 11 3367-7700  
faleconosco@fcmsantacasasp.edu.br

**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?
<a href="#">Protocol article</a>	protocol	09/07/2019	08/12/2020	Yes	No