

# Comparison between laparoscopic complete mesocolic excision versus standard laparoscopic colonic resection for right-sided colon cancer

<b>Submission date</b> 30/03/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/08/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A hemicolectomy is a surgical procedure that involves removing a segment of the colon, for example to treat colon cancer. The aim of this study is to compare the short-term outcomes of patients who undergo laparoscopic (keyhole surgery) right hemicolectomy using the CME and CVL technique (CME group) with patients who undergo conventional right-sided colonic resection (Not Complete Mesocolic Excision, NCME group).

### Who can participate?

Patients with right-sided colon cancer who are undergoing laparoscopic colonic resection (removal of the part of the colon containing the cancer)

### What does the study involve?

Participants are randomly allocated to undergo laparoscopic complete mesocolic excision with central vascular ligation (CME group) or laparoscopic standard right hemicolectomy (Not Complete Mesocolic Excision, NCME group). Both groups are followed up during their hospital stay or 30 days and long term to obtain results about ontological (cancer) outcomes.

### What are the possible benefits and risks of participating?

Possible benefits include better surgical outcomes in the CME group. Possible risks include a higher rate of complications in the CME group than the NCME group.

### Where is the study run from?

1. University Hospital Policlinico "P. Giaccone" of Palermo (Italy)
2. University of Palermo (Italy)

### When is the study starting and how long is it expected to run for?

October 2014 to December 2022

### Who is funding the study?

University of Palermo (Italy)

Who is the main contact?

1. Prof. Agrusa Antonino
2. Dr Giuseppe Di Buono  
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## Contact information

### Type(s)

Scientific

### Contact name

Dr Giuseppe Di Buono

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

LaCoMEStaR1

## Study information

### Scientific Title

Feasibility and safety of laparoscopic complete mesocolic excision (CME) for right-sided colon cancer: a prospective clinical study

### Acronym

LaCoMEStaR

### Study objectives

Laparoscopic complete mesocolic excision (CME) provides better surgical specimens than standard laparoscopic hemicolectomy.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Interventional single-centre study

**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**

Right-sided colon cancer

**Interventions**

Method of randomisation: cluster randomisation:

CME group (cases): laparoscopic complete mesocolic excision and central vascular ligation

NCME group (controls): standard laparoscopic right hemicolectomy

Follow-up: variable from short-term follow-up during hospital stay or 30-days in order to obtain feasibility and safety of laparoscopic CME versus NCME; long-term follow-up in order to obtain results about oncological outcomes.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

1. Operative time (skin-to-skin) in minutes, measured from medical records at the time of surgery
2. Intraoperative blood loss in mL, measured from medical records at the time of surgery
3. Other intraoperative complications: YES or NO and type of intraoperative complications (categorical variable), measured from medical records at the time of surgery
4. Conversion rate: YES or NO and percentage, measured from medical records at the time of surgery
5. Anastomotic leakage rate: YES or NO and percentage, measured from medical records during hospital stay
6. Specimen length: length in cm of surgical specimen, from histologic examination during 30

days

7. Lymph nodes harvesting: number of lymph nodes in surgical specimen, from histologic examination during 30 days

### **Secondary outcome measures**

Postoperative overall complications: YES or NO and type of postoperative complications (categorical variable), measured from medical records and radiologic imaging during hospital stay or 30 days

### **Overall study start date**

01/10/2014

### **Completion date**

31/12/2022

## **Eligibility**

### **Key inclusion criteria**

Patients with right-sided colon cancer

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

100

### **Total final enrolment**

132

### **Key exclusion criteria**

Open surgery, right colon resections for inflammatory bowel diseases (IBD) and associated major surgical procedures

### **Date of first enrolment**

01/01/2015

### **Date of final enrolment**

31/12/2019

## **Locations**

### **Countries of recruitment**

Italy

**Study participating centre**

**General and Emergency Surgery - University Hospital Policlinico "P. Giaccone"**

via L. Giuffrè, 5

Palermo

Italy

90127

## **Sponsor information**

**Organisation**

Azienda Ospedaliera Universitaria Policlinico "Paolo Giaccone" di Palermo

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.policlinico.pa.it/portal/>

**ROR**

<https://ror.org/05p21z194>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Università degli Studi di Palermo

**Alternative Name(s)**

Palermo University, University of Palermo

**Funding Body Type**

Government organisation

## Funding Body Subtype

Local government

## Location

Italy

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

## Intention to publish date

30/05/2020

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2021	11/08/2021	Yes	No