

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

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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

31/12/2022

Eligibility

Key inclusion criteria

Patients with right-sided colon cancer

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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

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?
Results article	results	01/07/2021	11/08/2021	Yes	No