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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

Registration date
07/04/2020

Overall study status
Completed

Last Edited
11/08/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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
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Sponsor information

Organisation
Azienda Ospedaliera Universitaria Policlinico "Paolo Giaccone" di Palermo

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