

Complete mesocolic excision vs. standard right hemicolectomy trial

Submission date 17/08/2016	Recruitment status Stopped	☒ Prospectively registered ☐ Protocol
Registration date 24/08/2016	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 30/12/2021	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
v1.0

Study information

Scientific Title
Complete Mesocolic Excision vs. standard of care right hemicolectomy randomised controlled Trial

Acronym
COMET

Study objectives

Complete mesocolic excision and central vascular ligation results in a larger specimen with more lymph nodes than standard of care right hemicolectomy surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Multi-centre cluster randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Right sided colonic adenocarcinoma

Interventions

Intervention - CME/CVL right hemicolectomy

Control - standard of care right hemicolectomy

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Size of resection specimen
2. Number of lymph nodes present

Key secondary outcome(s)

1. Operative time (minutes, intraoperative)
2. Blood loss (ml, intraoperative - swab weight and suction volume)
3. Length of hospital stay (postoperative days)
4. Early morbidity (30 day postoperative complications, Clavien-Dindo Classification, prospective observational recording from case notes and clinical team)
5. Surgical technique (open, laparoscopic or robotic, size of specimen, number of lymph nodes and above secondary outcomes)
6. Three year disease free and overall survival (observational recording from MDT records)
7. Specimens not compatible with CME/CVL surgery (Histopathological and/or operative video assessment - interventional arm only)
8. Extent of standard of care right hemicolectomy surgery (specimen size and number of lymph nodes, post-operative histopathological assessment)

Completion date

31/05/2019

Eligibility

Key inclusion criteria

1. Age 18+ years
2. Provision of written informed consent
3. Biopsy proven colonic adenocarcinoma located proximal to the mid transverse colon
4. Acceptable clear distal margin possible without division of the middle colic vessels
5. Local MDT recommends right hemicolectomy
6. Treatment undertaken with curative intent
7. Elective/scheduled operation
8. Patient assessed as fit for surgery
9. Minimal staging investigations performed - CT chest/abdomen/pelvis and full colonic assessment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patient refusal
2. Any neoadjuvant treatment (including stenting)
3. Treatment undertaken with palliative intent
4. Emergency surgery (unplanned resection within 48hrs of admission)
5. More extensive colonic resection surgery required or performed (extended right hemicolectomy - division of all middle colic vessels, subtotal colectomy)
6. R1/R2 on histopathological assessment

Date of first enrolment

01/10/2018

Date of final enrolment

01/05/2019

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
235 Euston Road
London
United Kingdom
NW1 2BU

Study participating centre
Queen Alexandra Hospital
Cosham
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Study participating centre
St Mark's Hospital
Northwick Park, Watford Road, Harrow
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HA1 3UJ

Study participating centre
Leeds Teaching Hospitals NHS Trust
St James's University Hospital
Leeds
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LS9 7TF

Study participating centre
Portsmouth Hospitals NHS Trust
Queen Alexandra Hospital
Southwick Hill Road
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Sponsor information

Organisation

Portsmouth Hospitals NHS Trust, UK

ROR

<https://ror.org/009fk3b63>

Funder(s)**Funder type**

Charity

Funder Name

Pelican Cancer Foundation

Alternative Name(s)

Pelicanfon

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request