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Complete mesocolic excision vs. standard right hemicolectomy trial

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

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

Study design
Multi-centre cluster randomised controlled trial

Primary study design
Interventional

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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Study participating centre
Leeds Teaching Hospitals NHS Trust
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Study participating centre
Portsmouth Hospitals NHS Trust
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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