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Complete mesocolic excision vs. standard right hemicolectomy trial

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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)

Overall study start date
02/01/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

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
England

United Kingdom

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
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
St Mark's Hospital
Northwick Park, Watford Road, Harrow
London
United Kingdom
HA1 3UJ

Study participating centre
Leeds Teaching Hospitals NHS Trust
St James’s University Hospital
Leeds

United Kingdom
LS9 7TF

Study participating centre
Portsmouth Hospitals NHS Trust
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust, UK

Sponsor details
De La Court House
Queen Alexandra Hospital
Portsmouth
England
United Kingdom
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Charity

Funder Name
Pelican Cancer Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/05/2020

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