ISRCTN15681041 https://doi.org/10.1186/ISRCTN15681041

LaCeS Feasibility: Laparoscopic versus open colorectal surgery in the acute setting

Submission date
18/04/2016

Recruitment status
No longer recruiting

Registration date
22/04/2016

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Emergency general surgery is one of the commonest reasons for admission to hospital. A wide range of problems can lead to an emergency admission, with diseases that affect the large bowel making up a third of diseases that present as an emergency. There is substantial evidence demonstrating the benefits of laparoscopic colorectal (keyhole surgery involving the lower part of the bowel) surgery for pre-planned (elective) surgery, with little equivalent evidence regarding its use in the emergency (acute) setting. Patients requiring emergency surgery present with a range of different health issues and diseases that has the potential to make laparoscopic surgery more technically challenging. The evidence from doing pre-planned operations may not be applicable to emergency surgery. It is therefore very important to test the role of laparoscopic surgery specifically when used in emergency surgery in order to provide an evidence base to aid clinical decision making. This study aims to determine the feasibility, safety and acceptability of performing a large-scale study comparing laparoscopic with open surgery for patients presenting with an emergency colorectal problem requiring resectional surgery (that is, requiring part of the bowel being removed).

Who can participate?
Adults aged at least 18 that need emergency resectional colorectal surgery.

What does the study involve?
Participants who agree to take part are randomly allocated to one of two groups. Those in group 1 receive laparoscopic surgery. Those in group 2 receive open surgery. Participants are not informed of what type of surgery they have received and do not know for 7 days after their surgery, or at point of discharge from hospital if earlier. Following their surgery, all participants are assessed at 3, 7 and 30 days after their surgery and then again at 3, 6 and 12 months after surgery. Participants are asked to complete questionnaires at the start of the study and also at all the assessment time points described above. Participants are expected to attend hospital for their follow up assessments. All patients who are approached for the trial, whether they agreed to take part or declined , are asked to complete a patient feedback questionnaire and also as to whether they would agree to be interviewed as part of a sub-study. The sub-study explores through interviews, patient and clinician acceptability of the study and method of recruitment.

What are the possible benefits and risks of participating?
The purpose of this study is to see ascertain if a larger study would be possible to compare laparoscopic and open emergency colorectal surgery. It is speculated that laparoscopic surgery could lead to reduced pain, shorter recovery time and reduced hospital stays therefore these are the potential benefits to participants that receive the laparoscopic surgery. All participants will need resectional bowel surgery and both types of surgery offered in the study are currently available as part of NHS routine practice, therefore the risks of participating should not be any different than of they were treated otherwise. Pre-operatively, participants will have a clinical review by their surgeon and a fitness for surgery assessment by the anaesthetist to assess suitability for both types of surgery. There is a high risk of complications in any emergency surgery however, it is not anticipated that these are increased by being part of the study.

Where is the study run from?
Five NHS hospitals in the UK:
1. St James University Hospital (lead centre)
2. Royal Victoria Infirmary (Newcastle upon Tyne)
3. Bradford Royal Infirmary
4. Morriston Hospital
5. Royal Gwent Hospital (Newport)

When is the study starting and how long is it expected to run for?
January 2016 to May 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Katie Gordon

Contact information

Type(s)
Public

Contact name
Mrs Katie Gordon

Contact details
Leeds Institute of Clinical Trials Research
Clinical Trials Research Unit
University of Leeds
Leeds
United Kingdom
LS2 9JT

Type(s)
Scientific

Contact name
Miss Deena Harji

Contact details
Northern Deanery
Newcastle Upon Tyne
United Kingdom
NE15 8NY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20790

Study information

Scientific Title
A multicentre, randomised controlled feasibility trial of Laparoscopic versus Open Colorectal Surgery in the Acute Setting

Acronym
LaCeS

Study objectives
The aim of this study is to assess the feasibility, safety and acceptability of performing a definitive phase III trial comparing laparoscopic and open colorectal surgery in the acute setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 01/02/2016, ref: 15/YH/0542

Study design
Randomised; Interventional; Design type: Treatment, Screening, Surgery

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Surgery, Primary sub-specialty: ; UKCRC code/ Disease:

Interventions
The intervention being assessed is the use of laparoscopic surgery for the treatment of acute colorectal pathology requiring resectional surgery, in the unplanned, acute setting. This involves the use of multiple small incisions to enable the introduction of instruments to be able to undertake the operation. The comparator is open surgery which is carried out through a large midline incision.

Randomisation will be performed using an automated 24 hour randomisation system accessed via the web or telephone. Patients will be randomised on a 1:1 basis to receive either laparoscopic or open surgery.

Following their trial surgery participants will be followed up for 12 months post operation, however the follow up period with end when the last randomised participant reaches 6 months post operation therefore not all patients will reach the 12 months follow up time point.

Intervention Type
Procedure/Surgery

Primary outcome measure
Feasibility: Quantitative assessment of recruitment rate, measured by numbers of patients screened, eligible and randomised each month.

Secondary outcome measures
1. Feasibility:
1.1. Practicality and acceptability of proposed recruitment and randomisation methods, assessed through qualitative patient and healthcare professional interviews and patient feedback questionnaires Feasibility of data collection required for a future phase III trial measured by the proportion of randomised patients with all the required baseline and follow-up assessments completed, number of withdrawals from follow-up data collection, reasons for withdrawal and number of losses to follow-up
1.2. Test and finalise the eligibility criteria to ensure homogeneity for a definitive phase III trial assessed by variability in baseline characteristics of randomised patients and queries that have arisen in relation to the eligibility criteria
1.3. Practicality and success of the blinding proposals in the acute setting assessed using the Bang Blinding Index for each arm, timings of unblindings, and through patient and healthcare professional interviews

2. Safety: Quantitative assessment of the safety profile of emergency laparoscopic colorectal surgery as measured by, conversion rates, intra- and post-operative complication rates, patient safety indicators rates and 30 day mortality rates

3. Endpoint Evaluation:
3.1. Establish the optimal outcome measure and it's timing to use as a primary endpoint, and also suitable secondary endpoints for evaluation in a phase III randomised controlled trial by measuring the variability of candidate primary and secondary endpoints (including HrQoL scores, pain scores, re-operative rates, re-admission rates, patient safety indicators, complication rates, mortality rates, length of hospital stay, restoration of gastrointestinal function) at candidate time-points (3, 7 and 30 days and 3, 6 and 12 months post-surgery and completion rates of candidate endpoints at candidate time points
3.2. Evaluation of optimal measures of safety assessed by variability and completion rates of measures of safety and full description of safety data collected

Overall study start date
01/01/2016

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1. Aged ≥ 18 years old
2. Diagnosis of acute colorectal pathology requiring resectional surgery (including acute diverticular disease, inflammatory bowel disease, large bowel obstruction and colonic perforation) confirmed on CT scan
3. NCEPOD classification urgency. Defined as intervention for acute onset or clinical deterioration of potentially life-threatening conditions, for those conditions that may threaten the survival of limb or organ. Normally within hours of decision to operate. Subdivided into NELA categories of 2a (approx. 2-6 hours) or 2b (approx. 6-18 hours)
4. Suitable candidate for surgery as judged by the operating surgeon.
5. Suitable for laparoscopic and open surgery in the opinion of the operating surgeon.
6. Suitable for laparoscopic and open surgery in the opinion of the anaesthetist.
7. Informed written consent obtained

Qualitative Patient Inclusion Criteria
1. Approached to consider entry into the LaCeS trial and either
1.1. Agreed to participate in the trial
1.2. Decided against participation after randomisation
1.3. Decided against participation when study presented to them
2. Willing and able to comply with requirements of this sub-study
3. Written informed consent obtained to participate in this sub-study

Qualitative Healthcare Professional Interview Inclusion criteria
1. Healthcare professional at a site taking part in the LaCeS trial either:
1.1. Recruiting staff involved in the LaCeS trial
1.2. Local Principal Investigator involved in the LaCeS trial
1.3. Local clinical staff involved in the LaCeS trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 66; UK Sample Size: 66

Total final enrolment
64

Key exclusion criteria
1. Haemodynamic instability requiring inotropic support
2. Acute non-
colorectal pathology (for example; small bowel obstruction, appendicitis, peptic ulcer disease).
3. Hand-assisted laparoscopic surgery.
4. Laparoscopy and peritoneal lavage alone for colorectal pathology.
5. Insertion of an endoscopic stent followed by laparoscopic resection for colorectal pathology.
6. Patients undergoing surgery for complications of elective colorectal operations
7. Pregnancy
8. Pre-existing cognitive impairment
9. Currently participating in another surgical trial

Qualitative Patient Exclusion Criteria
1. Decline participation in this sub-study
2. Unable to comply with requirements of this sub- study protocol

Healthcare Professional Exclusion Criteria
Refusal to participate in this sub-study

Date of first enrolment
21/07/2016

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
St James University Hospital (Lead Centre)
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Morriston
United Kingdom
SA6 6NL

Study participating centre
Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

Sponsor details
St. James's University Hospital
Beckett Street
Leeds
England
United Kingdom
LS9 7TF

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. We hope to publish the trial protocol once the trial has opened to recruitment (after July 2016)
2. Results of the study are intended to be reported in a peer reviewed scientific journal once data collection and data analysis is completed (after August 2018)

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/02/2018	04/02/2019	Yes	No
Results article	results	01/11/2020	03/03/2021	Yes	No
Other publications		02/11/2022	19/05/2023	Yes	No
HRA research summary			28/06/2023	No	No