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Open, laparoscopic and robotic radical cystectomy for bladder cancer

Submission date 23/09/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2014	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 17/05/2017	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Bladder cancer happens when a tumour develops in the lining of the bladder. Treatment for the condition depends on how advanced the cancer is and how much it has spread. If the cancer has spread to the muscle lining the bladder (i.e. it has become muscle-invasive) treatment may involve removing the entire bladder in an operation called a radical cystectomy. In some cases, it is now possible to have keyhole, or laparoscopic, surgery to remove the bladder. It is less invasive than the other two types of radical cystectomy surgery available (conventional and open abdomen surgery) as smaller cuts are made. To date, these three types of surgery have not been compared to see which one may be the most successful in curing the cancer or has the fastest recovery time. This study involves asking patients if they would agree to be randomly allocated to having one of the three types of surgery and following their progress while they are in hospital and after they have been discharged.

Who can participate?
Adults that are aged 18-80, have muscle-invasive bladder cancer and need a radical cystectomy.

What does the study involve?
Participants that agree to take part in the study are randomly allocated into one of three groups. Those in group 1 undergo conventional surgery. Those in group 2 undergo open abdomen surgery. Those in group 3 undergo laparoscopic surgery. They all receive the usual pre and post-surgery care. The progress of each participant is then followed while in hospital and they are asked to fill in questionnaires when they go to their local clinic for check-ups after discharge. The information gathered about their general health, test results and questionnaire answers is used to help decide which of the three types of surgery should be routinely offered to patients.

What are the possible benefits and risks of participating?
There are no particular risks or benefits associated with taking part in the trial, as this is an information gathering exercise. There are no new medicines or surgical tools to test as part of this study.

Where is the study run from?
Guys and St Thomas NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2008 to October 2013

Who is funding the study?
Guys and St Thomas NHS Foundation Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Contact details
The Urology Centre
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Additional identifiers

Protocol serial number
Version 1: August 2008

Study information

Scientific Title
A pilot randomized controlled trial of open, laparoscopic and robotic radical cystectomy for bladder cancer

Acronym
CORAL

Study objectives
Will patients permit random allocation to open or minimally invasive surgery to take out the bladder where there is no clear advantage offered by one surgical method over another in terms of operation success and shortened recovery time back to usual activity?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Guys and St Thomas Research Ethics Committee, 23/02/2009, ref: 08/H0804/135

Study design
Pilot randomised feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bladder cancer

Interventions
Patients consenting to participate were randomly assigned using the sealed envelope method to one of three surgical procedures (conventional, open abdominal surgery or laparoscopic or robot assisted minimal access surgery) to remove their bladder to cure cancer. All patients underwent a standardised Enhanced Recovery Pathway for radical cystectomy. Clavien methodology was utilised to record any adverse clinical issues for up to 30 days post-surgery. Outpatient care followed our standard procedures for post procedure imaging surveillance and all necessary nursing care of stomas etc.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. To determine the best methods of recruitment for the study, and the likely uptake of patients to facilitate future sample size estimates.
2. To determine patients and families likelihood of agreeing to participate in repeated interviews, the best time period for re-interview and the likely attrition from the study.

After discharge, all patients received routine clinical review at 2 weeks, 3, 6, and 12 months , and then yearly thereafter. Patient reported outcomes were sought using the validated questionnaire Functional Assessment of Cancer therapy - Bladder (FACT - BL) at each visit to clinic in their first year and yearly after that.

Key secondary outcome(s))
1. To determine the most appropriate methods of capturing data on symptoms, quality of life, preferences and experience among patients with the different methods of surgery to remove the urinary bladder
2. To determine the most appropriate methods of analysis of the study, in particular how to handle missing data due to attrition
3. To determine primary clinical outcome- composite complication rates such as transfusion, urine leakage, ileus, bowel leak/obstruction, cardiovascular and respiratory complications
4. To determine primary economic outcome: length of post-operative hospital stay (LOS)
5. To determine estimated blood loss, operative time
6. To determine economic evaluation: cost implications of clinical outcomes i.e., complications, LOS (based on unit daily cost of a NHS bed along with surgical, nursing and pharmaceutical support calculated at £500/day), blood loss, return to normal activity as studied by the physical and mental domains of the SF-8 questionnaire.
7. Economic modelling: Markov model and Monte Carlo simulation of the long term follow-up: 90-day readmission; 1-year potency in those previously potent; 1-year quality of life (SF-8); 2 year

metastasis rate; 5-year RFS
8. Sample size calculation 141 patients with 47 in each arm

As per local protocol, loopogram studies were performed at 3 months to assess for uretero-enteric anastomotic strictures. Computed tomography (CT) scans of the chest, abdomen and pelvis were performed at 6 and 12 months to assess for recurrence

Completion date
30/10/2013

Eligibility

Key inclusion criteria
1. Age 18–80
2. Sex–Male or female
3. Able to give informed consent
4. Proven muscle invasive bladder cancer or uncontrolled superficial bladder cancer requiring cystectomy .
5. Fit for major surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previous extensive abdominal or pelvic surgery
2. Previous treatment with external beam therapy or history of pelvic irradiation
3. Uncontrolled bleeding disorder
4. Unfit for major surgery
5. Unable to give informed consent
6. Pregnancy

Date of first enrolment
01/11/2008

Date of final enrolment
30/10/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Urology Centre
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guy's and St Thomas NHS Foundation Trust (UK)

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's and St Thomas' NHS Foundation Trust

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes