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Bladder cancer: Open versus Laparoscopic or RObotic cystectomy

Submission date 26/09/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/12/2008	**Overall study status** Completed	
Last Edited 21/01/2016	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-different-types-of-surgery-for-bladder-cancer-bolero

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01196403

Protocol serial number
SPON 568-08 (WCTU027)

Study information

Scientific Title
A study to determine the feasibility of randomisation to open versus minimal access cystectomy in patients with muscle invasive bladder cancer

Acronym
BOLERO

Study objectives
Open radical cystectomy is the standard surgical approach for patients with muscle-invasive bladder cancer. Cystectomy is a complex procedure associated with post operative morbidity of 30%, and UK in-hospital mortality as high as 5.6%. Complications related to open radical cystectomy include wound infection, delay in recovery of bowel function and delay in mobilisation. As a result the UK average in-patient stay is 20 days.

Minimal access radical cystectomy (laparoscopic or robotic) is emerging as an alternative to open radical cystectomy, and involves removal of the bladder through a small incision in the abdominal wall. Since the initial report more than 10 years ago, minimal access cystectomy has developed as a technique with potential for widespread application. However, there remain many unanswered questions relating to morbidity, procedure related complications, and oncological clearance. In addition, the perceived benefit of minimal access surgery by both patients and physicians may be an obstacle to recruitment into randomised controlled trials of minimal access cystectomy against the control arm of open radical surgery.

BOLERO aims to test whether it is feasible to randomise patients between open or minimal access cystectomy. The secondary aims will be to assess the safety and efficacy of minimal access cystectomy, and the reasons for non-acceptance of randomisation and/or registration. Exploratory aims will include the collection of safety and toxicity data, including measures of peri-operative morbidity and surgical complications. An exploratory assessment of anatomical lymph node dissection (an indicator for oncological clearance), quality of life, and completeness of cancer surgery will also be performed.

Minimal access is currently offered in each of the participating centres short-listed for this trial. Eligible patients will be identified through speciality MDTs and invited to partake in the trial. Patients will receive information describing open and minimal access cystectomy, and will be asked to consent to trial registration, and randomisation to one of two trial arms. Factors relating to a decision not to accept randomisation will be determined in a Qualitative Study. This will include qualitative assessment interviews of participants that do not agree to randomisation, and a review of screening logs to determine the reasons for non-registration. Peri-operative and in-patient exploratory assessments will be performed 6 weeks from date of discharge, then 3 monthly for 24 months. A quality of life assessment will also be performed in a subgroup of 20 participants, within 14 days of randomisation, and 4, 6 and 8 weeks, and 3, 6 and 12 months, after the date of cystectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Research Ethics Committee Panel D, 07/05/2010, ref: 09/WSE04/59

Study design
Late phase II randomised multi-centre feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Invasive bladder cancer

Interventions
Arm A: Open radical cystectomy
Arm B: Minimal radical cystectomy

Intervention Type
Procedure/Surgery

Primary outcome(s)
Feasibility of randomisation defined as >=60% of registered patients accepting randomisation to open versus minimal access cystectomy.

Key secondary outcome(s))
1. To determine the safety and efficacy of minimal versus open access cystectomy, including an assessment of the extent of lymph node dissection, short term morbidity and complications associated with surgery to open surgery
2. To determine the potential barriers to randomisation in patients who consent to registration and do not accept randomisation, via Quality Assessment interview of this patient pool
3. To determine potential factors relating to non-registration of patients with muscle invasive bladder cancer who are eligible for inclusion but have not been registered, based on review of screening logs

Timepoints of assessment for the secondary outcome measures 1-3 above have not been finalised as of 07/10/2008.

Exploratory outcome measures:
4. Morbidity assessment at 6 weeks from the date of discharge, then 3 monthly over a period of 24 months
5. Operative, peri-operative (<30 days) and late exploratory assessment (<180 days), including 90 and 180 day mortality
6. Oncological outcomes, including total number of lymph nodes resected and evidence of disease progression on CT scan at 6 and 12 months
7. Quality of life assessment using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and the muscle invasive bladder cancer module (EORTC QLQ-BLS24). Quality of life assessments will be performed in a subgroup of 20 participants, within 14 days of randomisation, 4, 6 and 8 weeks, and 3, 6 and 12 months after date of cystectomy.

Completion date
01/02/2013

Eligibility

Key inclusion criteria
1. Both males and females, aged >=16 years
2. American Society of Anaesthesiologists (ASA) score 1 or 2
3. Histopathological confirmation of urothelial cell carcinoma (UCC), squamous cell carcinoma (SCC) or adenocarcinoma of the bladder
4. pT1 or pT2, and mobile mass, on examination under anaesthesia
5. Computerised tomography (CT) scan of abdomen/pelvis indicating no enlarged nodes or distant metastases
6. If neo-adjuvant chemotherapy has been administered, surgery must be between 3 and 6 weeks from the last date of chemotherapy
7. Written, informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Prostatic urethral disease or upper tract disease
2. Concomitant disease that would render the patient unsuitable for the study
3. Presence of urosepsis

Date of first enrolment
17/01/2011

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College Hospital
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/01/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes