

# Bladder cancer: Open versus Laparoscopic or RObotic cystectomy

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|--|---|---|
| <b>Submission date</b><br>26/09/2008   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>11/12/2008 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>21/01/2016       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## 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

### Contact name

Prof John Kelly

### Contact details

University College Hospital  
235 Euston Road  
London  
United Kingdom  
NW1 2BU  
+44 (0)20 7380 9485  
[j.d.kelly@ucl.ac.uk](mailto:j.d.kelly@ucl.ac.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01196403

Secondary identifying numbers

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**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**

Invasive bladder cancer

**Interventions**

Arm A: Open radical cystectomy

Arm B: Minimal radical cystectomy

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Feasibility of randomisation defined as  $\geq 60\%$  of registered patients accepting randomisation to open versus minimal access cystectomy.

**Secondary outcome measures**

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.

**Overall study start date**

01/01/2009

**Completion date**

01/02/2013

## **Eligibility**

**Key inclusion criteria**

1. Both males and females, aged  $\geq 16$  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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

72

**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

England

United Kingdom

### Study participating centre

University College Hospital

London

United Kingdom

NW1 2BU

## Sponsor information

### Organisation

Cardiff University (UK)

### Sponsor details

Research and Commercial Division (RACD)

7th Floor

30-36 Newport Road

Cardiff

Wales

United Kingdom

CF24 ODE

### Sponsor type

University/education

### Website

<http://www.cf.ac.uk/racdv>

### 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, CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 19/01/2016   |            | Yes            | No              |