

# Quality of life after bladder cancer

<b>Submission date</b> 26/11/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/01/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/03/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Patients who have bladder cancer which has invaded the wall of the bladder, but not escaped further, can be treated with either radiotherapy or surgery. Radiotherapy is X ray treatment which is given daily over 4-6 weeks, allowing patients to keep their bladder. Surgery involves removal of the bladder (cystectomy) with either formation of a stoma (an opening onto the tummy wall, draining urine into a bag) or a new internal bladder formed from a section of bowel. Patients may be offered a choice between treatments but there is not a great deal of information about the reality of life after treatment to help them decide. This study aims to collect information from patients before and after treatment to help patients and health care teams understand the impact of treatment on quality of life. A separate part of the study will explore the financial costs to patients and the health service of each treatment.

### Who can participate?

Men and women aged 18 or over who have bladder cancer suitable for treatment with radiotherapy and surgery

### What does the study involve?

Participants either have radiotherapy or surgery as decided by them in conjunction with their healthcare team. Being in the study does not affect the treatment the participant receives. Participants complete questionnaires before treatment and at 6, 12 and 24 months from the end of treatment. The questionnaires ask about symptoms, quality of life and thoughts about the future. Participants can choose to be part of the health economics sub-study – if so they also complete a questionnaire about the costs of treatment and use of healthcare before treatment and at 3, 6, 9 and 12 months after treatment. The first questionnaires are completed at the hospital during normal visits but may take up to 20 minutes to complete. After treatment all the questionnaires are posted to participants homes to be completed at their convenience.

### What are the possible benefits and risks of participating?

Being in the study does not change standard treatment and so there are no additional side effects. There are no direct benefits in participating, although completing questionnaires may help participants identify problems. The risks of enrolling are that the questionnaires might trigger difficult or distressing thoughts. The questionnaires being used have been developed in patients with cancer and reviewed by patients involved in designing the study who have not identified any concerns. Support will be available for participants if distress occurs.

Where is the study run from?

The study is being run from Brighton & Sussex Hospitals. Approximately 35 centres across the UK will take part in the study.

When is the study starting and how long is it expected to run for?

August 2018 to May 2025

Who is funding the study?

The study is funded by Roche (a pharmaceutical company); Varian (a radiotherapy company) and two charities: the Sussex Cancer Fund & Fight Bladder Cancer.

Who is the main contact?

Isobelle Coombes (study manager)

Bsu-tr.qabc@nhs.net

## Contact information

### Type(s)

Scientific

### Contact name

Dr Isobelle Coombes

### Contact details

Research & Development Office

Brighton & Sussex University Hospitals NHS Trust

16 Bloomsbury House

Brighton

United Kingdom

BN1 2HQ

+44 (0)1273696955 ext 67893

Bsu-tr.qabc@nhs.net

## Additional identifiers

### Integrated Research Application System (IRAS)

246850

### Central Portfolio Management System (CPMS)

39645

## Study information

### Scientific Title

Quality of Life After Bladder Cancer (Q-ABC): a comparison of patient related outcomes following radical surgery and radiotherapy

### Acronym

Q-ABC V1.0

## **Study objectives**

Muscle invasive bladder cancer can be treated with radiotherapy or surgery. This study will explore the impact on quality of life.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

London (Surrey Borders), 25/09/2018, ref: 18/LO/1516

## **Study design**

Observational; Design type: Cohort study

## **Primary study design**

Observational

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Bladder cancer

## **Interventions**

This is an observational study collecting patient-reported quality of life questionnaires before and for 2 years following treatment for bladder cancer. It is not possible to randomise between these treatments (from a previous closed RCT) and so contemporaneous cohorts of patients are the best way of obtaining information that might be compared. 376 patients (188 in each treatment group) will be recruited in 25-35 centres across the UK.

Participants will be recruited before starting any treatment including chemotherapy (which may precede surgery or radiotherapy). They will complete questionnaires before treatment, after chemotherapy (if applicable) and then at 6, 12 and 24 months from the end of treatment.

The initial questionnaires will be completed at the hospital and from 6 months the questionnaires will be posted to participants. The questionnaires cover bladder cancer symptoms (FACT-BI), quality of life (FACT-BI & EQ-5D-5L) and thoughts about cancer recurrence (Fear of recurrence score) and it is estimated that these will take max 15 minutes to complete.

150 participants (of the 376, 75 from each group) will also be recruited to a health economic sub-study and asked to complete an additional questionnaire 3 monthly for the first year after treatment. This covers health service use and time off work/caring responsibilities to estimate societal costs (UK Cancer costs questionnaire). It is estimated that this will take 5-10 minutes to complete and the follow-up questionnaires will be posted to the participants.

Additional information will be collected by the local research nurses including disease and demographic characteristics and medical history at baseline. At 12 and 24 months research nurses will record any recurrence of bladder cancer, if the participant has died and what tests and appointments they have had in the last year. At 12 months the research nurse will complete with the participant (in person at their normal clinic visit or by phone) a symptom scoring questionnaire."

## **Intervention Type**

Other

## **Primary outcome(s)**

Quality of life is measured by the EQ-5D-5L and the FACT-BL questionnaires at baseline, 6, 12 and 24 months

## **Key secondary outcome(s)**

1. Participant characteristics measured using the study specific CRF which includes demographic information, cancer staging, 6 items from the CTCAE V5.0 and Charlson comorbidity index at baseline
2. Fear of recurrence measured using Kornblith fear of recurrence questionnaire at baseline, 12 and 24 months
3. Survival and recurrence rates measured via follow-up CRFs at 12 and 24 months
4. Clinician graded toxicity measured by a 5-item CTCAE V5.0 and patient reported toxicity via specific items on the FACT-BL questionnaire at 12 months
5. Costs calculated from hospital use (from CRF data about treatment and follow-up) and patient-reported costs via the UK Cancer Costs questionnaire completed at baseline and 3 monthly for the first year

## **Completion date**

31/05/2025

## **Eligibility**

### **Key inclusion criteria**

1. Aged  $\geq 16$  years, no upper age limit
2. Any patient undergoing potentially curative radical treatments for confirmed muscle invasive bladder cancer by either surgery or radiotherapy
3. Willing to provide informed consent
4. English Language competence sufficient to complete questionnaires

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Prior pelvic radiotherapy or surgery
2. Patients with bladder cancer other than transitional cell carcinoma
3. Patients who, in the judgement of the local PI, are not suitable for the study due to significant

mental health disorders or cognitive impairment

4. Previous malignancy in the last 5 years except for: non-muscle invasive bladder cancer; non-melanoma skin cancer, CIS of cervix or LCIS of breast

**Date of first enrolment**

13/10/2018

**Date of final enrolment**

31/03/2022

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**University Hospital of North Tees**

1st Floor, Middlefield Centre

Harwick

Stockton on Tees

United Kingdom

TS19 8PE

**Study participating centre**

**Mount Vernon Hospital**

Urology Research Team

Marie Curie Research Wing

Mount Vernon Cancer Centre

Upper West

Rickmansworth Road

Northwood

United Kingdom

HA6 2RN

**Study participating centre**

**Royal Sussex County Hospital**

CIRU

Eastern Road

Brighton

United Kingdom

BN2 5BE

**Study participating centre**

**Maidstone Hospital**

The Research Office  
Kent Oncology Centre  
Hermitage Lane  
Maidstone  
United Kingdom  
ME16 9QQ

**Study participating centre**

**Worthing Hospital**

Research & Innovation department  
135A, Park View  
Park Road  
Worthing  
United Kingdom  
BN11 2AP

**Study participating centre**

**Derriford Hospital**

Chestnut Unit, Level 7  
Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre**

**Addenbrookes Hospital**

Cambridge Cancer Trials Centre  
Cambridge University Hospitals NHS Foundation Trust  
Box 279(S4)  
Cambridge Biomedical Campus  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**

**Royal Oldham Hospital**

Ward C1  
Clinical Research Unit

Oldham  
United Kingdom  
OL1 2JH

**Study participating centre**  
**Musgrove Park Hospital**  
Clinical Research Oncology  
Beacon Centre  
Musgrove Park Hospital  
Taunton  
United Kingdom  
TA1 5DA

**Study participating centre**  
**Royal Lancaster Infirmary**  
Research & Development  
Pointer Court  
Lancaster  
United Kingdom  
LA1 4RP

**Study participating centre**  
**Royal Cornwall Hospital**  
Oncology Trials  
Sunrise Centre  
Royal Cornwall Hospitals NHS Trust  
Treliske  
Truro  
United Kingdom  
TR1 3LJ

**Study participating centre**  
**Sunderland Royal Hospital**  
Clinical Trials Office  
Floor E  
City Hospitals Sunderland NHS Foundation Trust  
Kayll Road  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**  
**Clatterbridge Cancer Centre**  
Research & Innovation Dept  
Clatterbridge Road  
Bebington  
United Kingdom  
CH63 4JY

**Study participating centre**  
**Queen's Hospital**  
Cancer Trials Office  
Ground Floor  
Orange Zone  
Rom Valley Way  
Romford  
United Kingdom  
RM7 0AG

**Study participating centre**  
**Peterborough City Hospital**  
North West Anglia NHS Foundation Trust  
Oncology Research Department 018  
Haematology/Oncology Day Unit  
Edith Cavell Campus  
Bretton Gate  
Peterborough  
United Kingdom  
PE3 9GZ

**Study participating centre**  
**Stepping Hill Hospital**  
Ward C2  
Research & Innovation  
Stockport NHS Foundation Trust  
Poplar Grove  
Stockport  
United Kingdom  
SK2 7JE

**Study participating centre**  
**Eastbourne District General Hospital**  
East Sussex Healthcare NHS Trust  
Clinical Research Dept

Polgate Ward  
Kings Drive  
Eastbourne  
United Kingdom  
BN21 2UD

**Study participating centre**

**Ipswich Hospital**

Cancer Research Office  
Oncology, N045  
Heath Road  
Ipswich  
United Kingdom  
IP4 5PD

**Study participating centre**

**Tameside General Hospital**

Tameside & Glossop Intergrated Care NHS Foundation Trust  
Fountain Street  
Ashton Under Lyne  
United Kingdom  
OL6 9RW

**Study participating centre**

**Norfolk & Norwich University Hospital**

Norfolk & Norwich Univerity Hospital  
Colney Lane  
Norwich  
United Kingdom  
NR4 7UY

**Study participating centre**

**Royal Blackburn Hospital**

East Lancashire Hospitals NHS Trust  
Cancer Reseach Office  
Room 3.43, 2nd Floor  
Park View Offices  
Haslingden Road  
Blackburn  
United Kingdom  
BB2 3HH

**Study participating centre**  
**Royal Preston Hospital**  
Lancashire Clinical Research Facility  
Avondale Unit  
Royal Preston Hospital  
Sharoe Green Lane  
Fulwood  
Preston  
United Kingdom  
PR2 9HT

## Sponsor information

**Organisation**  
Brighton and Sussex University Hospitals NHS Trust

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
F. Hoffmann-La Roche

**Alternative Name(s)**  
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
For-profit companies (industry)

**Location**  
Switzerland

**Funder Name**  
Varian Medical Systems

**Alternative Name(s)**  
Varian Medical Systems, Inc., Varian Associates,

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

**Funder Name**

Fight Bladder Cancer

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ashok Nikapota. Anonymised aggregate level data, available after study publication, access to be determined by trial management group for specific purposes on a case by case basis.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			26/07/2023	No	No