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Quality of life after bladder cancer

Submission date
26/11/2018

Recruitment status
No longer recruiting

Registration date
25/01/2019

Overall study status
Completed

Last Edited
16/03/2024

Condition category
Cancer

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

EudraCT/CTIS number

IRAS number
246850

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 39645, IRAS 246850

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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

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

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

Interventions
This is a 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-Bl), quality of life (FACT-Bl & 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 measure
Quality of life is measured by the EQ-5D-5L and the FACT-Bl questionnaires at baseline, 6, 12 and 24 months

Secondary outcome measures
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

Overall study start date
09/08/2018

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. Aged ≥ 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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 376; UK Sample Size: 376

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
England

United Kingdom

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

Sponsor details
Royal Sussex County Hospital
Eastern Road
Brighton
England
United Kingdom
BN2 5BE
+44 (0)1273 696955 x7497
scott.harfield@bsuh.nhs.uk

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
1. Planned publication in a high impact peer-reviewed journal
2. Presentation at conferences
3. Dissemination via national patient charity (Fight Bladder Cancer)

Intention to publish date

31/05/2026

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?
HRA research summary			26/07/2023	No	No