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Quality of life after bladder cancer (Q-ABC)

Submission date 20/03/2017	**Recruitment status** No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/04/2017	**Overall study status** Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/02/2022	**Condition category** Cancer	☐ Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-quality-of-life-after-bladder-cancer-q-abc-qis

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
Quality of Life After Bladder Cancer - a qualitative interview study (Q-ABC-QIS)

Study objectives
The aim of this study is to use in depth interviews to explore the “lived experience” of patients and carers who have undergone, or supported someone through, treatment for bladder cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Coast: Brighton & Sussex REC, 01/02/2017, ref: 16/LO/1638

Study design
Non-randomised; Observational; Design type: Qualitative

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Bladder Cancer; UKCRC code/ Disease: Cancer/ Malignant neoplasms of urinary tract

Interventions
Participants will have a single interview lasting approximately one hour. This will be at their home or hospital depending on the preference of the participant. There is no follow-up.

The interview takes place 1-2 years after treatment. The interview involves discussion of how the cancer and treatment have impacted on their (for patients)/their relative/friend’s and their own (for carers) quality of life, including physical and emotional changes. The discussion will also cover their (for patients)/their relative/friend’s experience of deciding between treatments, if a choice was offered.

Intervention Type

Other

Primary outcome measure
Quality of Life of patients and carers following radical treatment for bladder cancer, explored using interviews, at a single time point between 1-2 years post treatment.

Secondary outcome measures
1. Experience of the decision-making process relating to radical treatment for bladder cancer, explored using interviews, at a single time point between 1-2 years post treatment
2. Comparative experience of patients and carers, explored using interviews, at a single time point between 1-2 years post treatment

Overall study start date
01/03/2016

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Adult patients > 18 years
2. Diagnosis of Muscle invasive bladder cancer
3. Treated with either radical cystectomy or radical (chemo-)radiotherapy between 1 and 2 years prior to study.
4. English speaking sufficient for in depth interview

Carer:
1. Informal carer of a person who fulfils 1-3 above (recognising that this person may no longer fulfil a “caring” role but did so during treatment)
2. English speaking sufficient for in depth interview

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
Recurrent disease

Date of first enrolment
02/01/2017

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Sussex County Hosptial
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Eastbourne District General Hospital
Kings Drive
Eastbourne
United Kingdom
BN21 2UD

Study participating centre
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

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 1273 696955 ext 7497
scott.harfield@bsuh.nhs.uk

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
Pelican Cancer Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Findings will be submitted for publication in high-impact peer reviewed journals.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from sally.appleyard@bsuh.nhs.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.3	01/11/2016	21/04/2017	No	Yes
Participant information sheet	version V1.1	01/11/2016	21/04/2017	No	Yes
Results article		01/06/2021	18/02/2022	Yes	No
HRA research summary			28/06/2023	No	No