Quality of life after bladder cancer (Q-ABC)

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

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

Contact name

Ms Sally Appleyard

ORCID ID

http://orcid.org/0000-0001-8167-8048

Contact details

Clinical Investigation & Research Unit Royal Sussex County Hospitals Eastern Road Brighton United Kingdom BN2 5BE +44 sally.appleyard@bsuh.nhs.uk

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 |