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Electronic data collection of QoL PROMS in Prostate cancer

Submission date 21/11/2016	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/12/2016	**Overall study status** Completed	
Last Edited 28/06/2019	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-new-way-to-learn-about-the-quality-of-life-of-men-with-prostate-cancer#undefined

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
32084

Study information

Scientific Title
Electronic data capture of Health Related Quality of Life Patient Reported Outcome Measures (PROMS). An exploratory study in Patients with Prostate Cancer.

Acronym
PROMS

Study objectives
The aim of this study to explore whether patients are willing and able to complete questionnaires to asses quality of life on a tablet computer, so that the information is entered electronically by the patient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central- Hampshire A, 05/07/2016, ref: 16/SC/0289

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
Participants will be asked to complete questionnaires relating to quality of life on a tablet computer – EORTC QLQ C30 (generic quality of life), EORTC PR25 (Prostate cancer specific module) and EQ-5D-5L (brief quality of life scale used to calculate QALYs).

Visit 1 takes place before commencing treatment and takes place either in clinic or at first treatment appointment. Meet Research Fellow and complete informed consent. Research fellow to complete demographics and “computer familiarity” questionnaires (paper). Participant to complete QoL questionnaires on tablet computer with support from Research Fellow if needed. Research fellow to complete “feasibility” paper questionnaires.

Visit 2 takes place 3 months from the start of treatment, and involves either an in clinic or at treatment appointment (meet research fellow and complete QoL questionnaires as above on tablet. Research fellow to complete feasibility questionnaire) or for the participant to complete questionnaires at home following an email reminder (esearch fellow to complete feasibility questionnaire either in person (at clinic or treatment appointment) or by phone).

Optional remote completion
At 1 and 2 months from start of treatment participants complete QoL questionnaires at home – following email reminder – either on desktop/laptop via web-based interface or on a mobile phone/tablet on an app.

Total duration of intervention = 3 months, no study follow-up beyond that date.

Intervention Type
Other

Primary outcome(s)
Feasibility will be assessed by measuring the time taken to complete the questionnaire (collected by electronic data collection system), patient reported feasibility (via feasibility questionnaire) and support needed from the researcher (via feasibility questionnaire) at baseline and 3 months, and measuring the rate of questionnaire completion at 3 months.

Key secondary outcome(s))
1. Health care professional reported feasibility (all clinic staff including recruiting oncologists) is measured via a HCP feasibility questionnaire at the end of the study
2. Uptake rate (impressions from recruiting doctors(is obtained from HCP feasibility questionnaire at the end of the study
3. Comparison with clinical decision at 3 months is assessed via comparison with decision whether or not to continue treatment and PSA measurement
4. Suitability of tools (sensitivity of tools to change in QoL) is measured via comparison between tools

Completion date
31/07/2017

Eligibility

Key inclusion criteria
1. Adult patients > 18 years
2. Diagnosis of prostate cancer not suitable for radical (curative) treatment
3. Commencing palliative systemic therapy (first or subsequent lines) – cytotoxic chemotherapy, modern hormonal agents (including enzalutamide and abiraterone) and radium 223.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

Male

Total final enrolment
40

Key exclusion criteria
1. Already commenced treatment
2. Treated with androgen deprivation therapy, stilboestrol or dexamethasone only.
3. Treated with trial treatments that are not NICE or Cancer Drug Fund approved

Date of first enrolment
06/09/2016

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Sussex County Hosptial
Clinical Investigation & Research Unit
Eastern Road
Brighton
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Study participating centre
Eastbourne District General Hospital
Kings Drive
Eastbourne
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BN21 2UD

Study participating centre
Worthing and Southlands Hospitals
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Sponsor information

Organisation
Brighton and Sussex University Hospitals NHS Trust

Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis

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 Sally Appleyard (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?
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1.2	22/11/2016	05/12/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes