

Electronic data collection of QoL PROMS in Prostate cancer

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

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

Contact name

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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 assess 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

Primary study design

Observational

Study design

Observational; Design type: Cohort study

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 (research 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 Hospital

Clinical Investigation & Research Unit
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 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