

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Observational; Design type: Cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

See additional files

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/10/2015

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

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

Planned Sample Size: 40; UK Sample Size: 40

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**

England

United Kingdom

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

Sponsor details

Royal Sussex County Hospital
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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Industry

Funder Name

Sanofi-Aventis

Results and Publications

Publication and dissemination plan

Planned publication in Clinical Oncology.

2017 results presented at the NCRI Cancer Conference in <http://abstracts.ncri.org.uk/abstract/electronic-data-capture-of-qol-proms-an-exploratory-study-in-patients-commencing-palliative-treatment-for-prostate-cancer/>.

Intention to publish date

31/12/2017

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