

Study assessing the impact of depression and anxiety on prostate cancer patients' quality of life

Submission date 02/07/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/07/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/07/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Prostate cancer is the most common male cancer. Hormone therapy, in form of testosterone deprivation, plays an important role in the treatment of both early and metastatic prostate cancer. However, the hormonal treatment of prostate cancer is associated with significant psychological illness. The extent, severity and the natural course of the psychological side effects have not been well studied. This study aims to evaluate the psychological effects of hormonal treatment using questionnaires and scales. This study also aims to validate the 'ageing male symptoms scale' in prostate cancer patients on hormonal treatment.

Who can participate?

Male patients on hormone therapy for prostate cancer

What does the study involve?

Psychological side effects and symptoms are assessed using questionnaires. Before they begin their hormone treatment, participants will be given a complete physical examination and their medical history will be taken. Participants complete questionnaires and undergo a full physical examination during and after hormone therapy. Blood samples (about two tablespoons per visit) will also be taken. Many of these blood tests would have been routinely done as part of follow up visits.

What are the possible benefits and risks of participating?

There is no intended clinical benefit. It is hoped that the information from this study will benefit other patients with prostate cancer in the future. There are no expected risks. The main possible disadvantage would be the time involved in completing the questionnaires.

Where is the study run from?

Nottingham University Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for?

June 2002 to December 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Santhanam Sundar
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
REC ref: 05/Q2403/8

Study information

Scientific Title
Prospective assessment of psychological and vasomotor side effects of testosterone deprivation and assessment of ageing males' symptoms scale in prostate cancer patients

Acronym
Prostate QOL

Study objectives
Prospective assessment of psychological and vasomotor side effects of testosterone deprivation and development of an andropause rating scale

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 01/03/2005, Nottingham LREC Committee (NHS Nottingham level 3, 1 Standard Court, Park Row, Nottingham, NG1 6GN, UK; +44 (0)115 912 3344 ext 49435; linda.ellis@rushcliffe-pct.nhs.uk), REC ref: 05/Q2403/8

Study design

Prospective observational longitudinal single-centre study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Patients were administered quality of life (QOL) questionnaires and rating scale questionnaires at specific time points before, during and after completion of hormone therapy. Hormone therapy duration was variable mainly due to baseline clinical features such as Tumour stage, PSA and Pathological features, and in a minority of patients due to subsequently identified clinical need

Intervention Type

Other

Primary outcome(s)

Measured before, during and after completion of hormone therapy:

1. Anxiety and depression measured using the Hospital Anxiety and Depression Scale
2. Severity of symptoms related to aging measured using the Aging Males' Symptoms (AMS) scale
3. Quality of life measured using the EORTC QLQ-C30 questionnaire
4. Symptoms measured using the non-specific symptom (NSS) checklist
5. Health anxiety measured using the Whiteley Index
6. Erectile dysfunction measured using an abridged version of the IIEF SCALE

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/12/2021

Eligibility

Key inclusion criteria

1. Patients with prostate cancer starting LHRH agonist therapy, irrespective of stage
2. Ability to give informed consent
3. Performance status 0-2
4. Life expectancy should be more than 6 months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Total final enrolment

150

Key exclusion criteria

1. Past or present history of psychiatric problem
2. If a patient scores greater than 11 on the baseline Hospital and Anxiety Scale they will be offered anti-depressant drug treatment and/or a psychiatric referral. In addition they will be asked if they wished to continue in the study. If the patients do not wish to continue at this stage the researchers would not collect any further quality of life information from them
3. Concurrent steroid therapy or treatment with any other antipsychotic/antidepressant /sedative drugs
4. Brain metastases
5. Concurrent radiotherapy
6. Major surgery in last 6 months, e.g. prostatectomy, colectomy etc
7. Major medical illness in last 6 months e.g. pulmonary embolism, myocardial infarction, cerebrovascular accident etc

Date of first enrolment

01/03/2005

Date of final enrolment

30/04/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Nottingham City Hospital

Nottingham University Hospitals NHS Trust

Hucknall Road

Nottingham

United Kingdom

NG5 1PB

Sponsor information

Organisation

Nottingham University Hospitals NHS Trust

ROR

<https://ror.org/05y3qh794>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The data may be available from Dr Santhanam Sundar (sundar@oncology.org) after the researchers have analysed and published the data in PubMed-listed journals (the main paper and any associated hypothesis-generating papers based on the study data).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			26/07/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3	01/06/2009	26/07/2021	No	No