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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	[_] Prospectively registered [X] Protocol
Registration date 27/07/2021	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 27/07/2021	**Condition category** Cancer	[_] Individual participant data [_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files

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 measure
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 dysunction measured using an abridged version of the IIEF SCALE

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/06/2002

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

Age group
Adult

Sex
Male

Target number of participants
150

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
England

United Kingdom

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

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Hucknall Road
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Sponsor type
Hospital/treatment centre

Website
https://www.nuh.nhs.uk/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
1. Presentation at national and international conferences
2. Peer-reviewed publications

Intention to publish date
31/12/2021

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
Protocol file	version 3	01/06/2009	26/07/2021	No	No