

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

<b>Submission date</b> 02/07/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/07/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/07/2021	<b>Condition category</b> 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  
Santhanam.Sundar@nuh.nhs.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Santhanam Sundar

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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](mailto: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?
<a href="#">Participant information sheet</a>			26/07/2021	No	Yes
<a href="#">Protocol file</a>	version 3	01/06/2009	26/07/2021	No	No