

How do waiting times during diagnosis affect psychological and physiological stress in men with suspected prostate cancer?

Submission date 26/06/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/11/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/01/2025	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

The diagnosis process for suspected prostate cancer is emotionally straining for patients and may, in itself, have negative health implications. Considerable variability in waiting-time during the diagnosis processes exists, but data are scarce on how it may affect the patients' distress level. In this clinical trial, we aim to compare stress-related symptoms and biomarkers during the diagnostic workup process among men with suspected prostate cancer who are randomized to either a fast-track diagnostic workup process or to usual care workup at the Urology Department at Örebro University Hospital in Sweden.

Who can participate?

Males aged 85 years or less with suspected prostate cancer referred to the Urology Department at Örebro University Hospital.

What does the study involve?

The study involves randomization of men with suspected prostate cancer to either a fast-track diagnostic workup process or to usual care diagnostic workup. The participants' stress levels are assessed at different time points during and after the diagnostic workup process, using questionnaires focused on self-reported symptoms of distress (anxiety, depression, distress, sleep disruption). Stress levels are further characterized through the repeated collection of saliva samples for assessment of diurnal cortisol patterns as well as thumb-ECGs for measurement of heart rate variability.

What are the possible benefits and risks of participating?

The possible benefits and risks of participating relate to reduced or increased stress levels and the potentially stress-linked health risk, respectively. The variation in duration of the workup and related potential treatment delay is not expected to influence the disease course.

Where is the study run from?

Örebro University Hospital, Sweden

When is the study starting and how long is it expected to run for?
April 2015 to December 2021

Who is funding the study?
Swedish Cancer Foundation

Who is the main contact?
Dr Katja Fall
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
266361 (FOU ÖREBRO)

Study information

Scientific Title
Prostate cancer Stress Surveillance and Survival (ProCeSS): evaluation of a fast-track clinical workup for men with suspected prostate cancer

Acronym
ProCeSS

Study objectives
Waiting time during diagnostic workup for suspected prostate cancer effects psychological and physiological measures of stress relevant to health and disease

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 11/11/2014, Ethics review board Örebro University Hospital (Örebro läns landsting, Box 1613, 701 16, Örebro, Sweden; Registrar@uppsala.epn.se; +46 18 4717400) ref: 2014/348 /1

Study design

Randomized clinical trial double-blind single-centre

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Men with suspected prostate cancer are randomized to regular or fast-track diagnostic work-up.

The fast-track intervention entails a diagnostic workup process where the shortest possible waiting-time is targeted: 1 week between randomization and the urologist visit with biopsy (if needed), 1 week between biopsy and diagnosis, and 1 week between diagnosis and treatment decision. The usual care group has waiting-times of approximately 1 week to 3 months, about 2 weeks, and 2 weeks during these steps, respectively. Men in both arms are first assessed at the urology clinic directly after randomization and again during a first urologist visit where a diagnostic biopsy is taken. Subsequent assessments are made 1, 6 and 12 months after randomization.

Written informed consent is obtained by a research nurse before participants are randomized to either fast-track workup or to usual care. Group assignment cards, which have been randomly placed into sealed envelopes, are drawn for allocation of management. All participants are informed that their experience of the diagnostic work-up process is assessed, and that they will be blinded with regard to study group. A research nurse registers the assignment group and arranges the workup process according to the assigned management. The assigned treatment group is therefore not revealed to either urologist or patient.

Intervention Type

Other

Primary outcome(s)

At baseline, 1, 6 and 12 months:

1. Depression and anxiety with the Hospital Anxiety and Depression Scale (HADS)
2. Self-evaluated distress with the National Comprehensive Cancer Network (NCCN) distress thermometer
3. Sleep quality and disturbances through the Åkerstedts Karolinska Sleep Questionnaire

Key secondary outcome(s)

At baseline, 1, 6 and 12 months:

1. Heart rate variability measured using thumb-ECG
2. Diurnal cortisol level measured using saliva cortisol

Completion date

31/12/2022

Eligibility

Key inclusion criteria

1. Referred to the Urology Department at Örebro University Hospital for suspected prostate cancer
2. Male
3. Aged 85 years or younger
4. Able to speak and write Swedish

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

Male

Key exclusion criteria

1. Signs of advanced prostate cancer. Metastatic prostate cancer and cancer with prostate-specific antigen level (PSA) >100 mg/l are defined as advanced prostate cancer
2. Severe psychiatric or somatic diseases
3. Any other malignancy

Date of first enrolment

14/04/2015

Date of final enrolment

31/12/2021

Locations

Countries of recruitment

Sweden

Study participating centre

Örebro University Hospital

Södra Grev Rosengatan

Örebro

Sweden

70185

Sponsor information

Organisation

Örebro University Hospital

ROR

<https://ror.org/02m62qy71>

Funder(s)

Funder type

Charity

Funder Name

Swedish Cancer Foundation

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Psychological and physiological impacts of a fast-track diagnostic workup for men with suspected prostate cancer: Preliminary report from a randomized clinical trial	07/04/2020	21/01/2025	Yes	No