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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

Registration date
22/11/2019

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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
Katja.Fall@oru.se

Contact information

Type(s)
Scientific

Contact name
Dr Katja Fall

ORCID ID
http://orcid.org/0000-0002-3649-2639

Contact details
Södra Grev Rosengatan
Örebro
Sweden
70185
+46 (0)19-6023162
Katja.Fall@oru.se

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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; Registrator@uppsala.epn.se; +46 18 4717400) ref: 2014/348 /1

Study design
Randomized clinical trial double-blind single-centre

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web-format, please use contact details to request a participant information sheet.

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 measure
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

Secondary outcome measures
At baseline, 1, 6 and 12 months:
1. Heart rate variability measured using thumb-ECG
2. Diurnal cortisol level measured using saliva cortisol

Overall study start date
06/11/2014

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

Age group
Mixed

Sex
Male

Target number of participants
400

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

Sponsor details
Urology Deparment
Södra Grev Rosengatan
Örebro
Sweden
70185
+46 196021000
info@regionorebrollan.se

Sponsor type
Hospital/treatment centre

Website
https://www.regionorebrolan.se/sv/uso/Patientinformation/Kliniker-och-enheter/Urologiska-kliniken/

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

Publication and dissemination plan
Peer-reviewed international scientific journals.

A protocol written in Swedish can be made available upon request from the study contact.

Intention to publish date
01/01/2023

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