

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

<b>Submission date</b> 26/06/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/11/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/01/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English Summary

### 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**

### **Study hypothesis**

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.

### **Condition**

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

### **Overall study end date**

31/12/2022

## **Eligibility**

### **Participant 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

### **Participant 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

**Recruitment start date**

14/04/2015

**Recruitment end date**

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 Department

Södra Grev Rosengatan

Örebro

Sweden

70185

+46 196021000

info@regionorebrollan.se

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.regionorebrollan.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?
<a href="#">Other publications</a>	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