

# SPCG-17 - when to treat men who are in active surveillance for prostate cancer, a randomized study comparing current practice with standardized triggers for initiation of curative treatment

<b>Submission date</b> 05/09/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 20/09/2016	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/12/2024	<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 cancer in men in the Western world. If prostate cancer is detected when it is at an early stage and not causing any symptoms, treatment is not immediately needed. Instead the patient's condition is carefully monitored (active surveillance) with blood tests (the PSA test), physical examination of the prostate, and taking a small sample of tissue (a biopsy) from the prostate. There is however a problematic knowledge gap surrounding active surveillance, and the most important piece of evidence missing is when treatment is likely to be needed and beneficial for the patient. Moreover, the optimal follow-up programs are not yet defined. The aim of this study is to compare current practice of active surveillance with a standardised program for follow-up and triggers for treatment. It is believed that standardised criteria for treatment will reduce unnecessary treatment of early stage prostate cancer, without increasing the risk of not being cured in time. Patients can safely be followed-up by nurses, which increase continuity. Standardised, evidence-based active surveillance programs can also decrease inequities of health care in and between countries.

### Who can participate?

Scandinavian and British men with untreated low-risk or favourable intermediate-risk prostate cancer, eligible for active surveillance

### What does the study involve?

Participants are randomly allocated to one of two equally sized groups. One group is monitored according to current clinical practice at the clinic where the participant is a patient. The other group is monitored according to a standardised program where treatment is initiated only when specific criteria are fulfilled. Both groups undergo a standard set of prostate biopsies and an MRI examination of the prostate upon inclusion in the study, and are then followed in the same way with PSA testing every 6 months, a yearly clinical check-up, and an MRI examination of the

prostate every 2 years. In the clinical practice group, further biopsies and tests can be performed according to the urologist's judgement.

What are the possible benefits and risks of participating?  
Not provided at time of registration

Where is the study run from?

The study is run from Uppsala University (Sweden), and a number of hospitals in Sweden, Norway, Denmark, Finland and the UK will enrol patients into the study.

When is the study starting and how long is it expected to run for?  
June 2016 to December 2040

Who is funding the study?

1. The Swedish Cancer Society
2. Swedish research council
3. Nordic Cancer Union

Who is the main contact?

Professor Anna Bill-Axelsson  
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## Contact information

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Public

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

NCT02914873

### Protocol serial number

Nil known

## Study information

### Scientific Title

SPCG-17 - Prostate Cancer Active Surveillance Trigger Trial (PCASTT)

### Study objectives

The study hypothesis is that standardized triggers for initiation of curative treatment of men who are in active surveillance will reduce over-treatment without increasing disease progression and prostate cancer mortality.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Regional Ethical Vetting Board in Uppsala, Sweden, 15/06/2016, ref: 2016/204

### Study design

Randomized multi-centre open-label clinical trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Active surveillance for low-risk and favourable intermediate-risk prostate cancer

### Interventions

Current interventions as of 11/06/2019:

Computerized randomisation (1:1) within 12 months from diagnosis of prostate cancer, either to active surveillance according to current practice at the trial centre (reference arm), or to a standardised active surveillance protocol applying specific criteria for initiating curative treatment (experimental arm).

Patients are stratified by centre and Gleason score.

Follow-up in the reference arm (current practice at the trial centre): PSA every 6 months, clinical examination (with PSA test) annually, and MRI (with targeted biopsies at suspicious lesions) every second year. Repeat biopsies and/or other examinations can be initiated according to the urologist's judgement.

Follow-up in the experimental arm (criteria for intervention): PSA every 6 months, clinical examination (with PSA test) annually, and MRI (with targeted biopsies at suspicious lesions) every second year. Repeat biopsies and/or curative treatment is initiated if specific criteria are fulfilled (see below).

Criteria for repeat biopsies (experimental arm only):

1. A systematic repeat biopsy if PSA density increases to  $> 0.2$  ng/ml/cc
2. MRI progression in men with previously only Gleason grade 3+3 (5 mm or more increase in size in any dimension of a measurable lesion, increase in PI-RADS score to 3-5, high or very-high suspicion of extra-capsular extension or seminal vesicle invasion, or a new lesion with PI-RADS score 3-5)
3. MRI progression in men with Gleason grade 3+4 (5 mm or more increase in size in any dimension of a measurable lesion, or a new lesion with PI-RADS score 3-5)

Criteria for curative treatment (experimental arm only):

1. MRI progression in lesions with confirmed Gleason grade 4 (increase in PI-RADS score to 4 or 5, or high or very-high suspicion of extra-capsular extension or seminal vesicle invasion)
2. Pathological progression (Gleason pattern 5, primary Gleason pattern 4 in any core with 5 mm or more cancer, Gleason 3+4 in 3 or more cores or 30% if more than 10 cores are taken, or Gleason 3+4 in 10 mm or more cancer)

Patients will be followed continuously until initiation of treatment, the event of metastasis, to a break point where active surveillance is considered terminated and watchful waiting starts, or to death of any cause. After the initiation of curative treatment, watchful waiting, or palliative treatment for cancer progression, the patient is followed according to the standard protocol of the participating centre.

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2. MRI progression in men with previously only Gleason grade 3+3 (5 mm or more increase in size in any dimension of a measurable lesion, increase in PI-RADS score to 3-5, new suspicion of extra-capsular extension or seminal vesicle invasion, or a new lesion with PI-RADS score 3-5)
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Criteria for curative treatment (experimental arm only):

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## **Intervention Type**

Other

## **Primary outcome(s)**

Current primary outcome measure as of 15/12/2024:

The primary outcome is disease progression, defined as 1) cumulative incidence of PSA relapse after curative treatment or 2) cumulative incidence of androgen deprivation therapy in untreated men still in active surveillance.

The first analysis for the primary endpoint will be performed 1 year after inclusion of the last patient into the study. Subsequent analyses for primary (and secondary) endpoints will be performed every 3 years.

Previous primary outcome measure:

The primary outcome is progression-free survival, which is defined as cumulative incidence of PSA relapse after curative treatment and cumulative incidence of androgen deprivation therapy in untreated men.

The first analysis for the primary endpoint will be performed 1 year after inclusion of the last patient. Subsequent analyses for primary (and secondary) endpoint will be performed every 3 years. Final outcome at 10 years is cumulative prostate cancer mortality.

## **Key secondary outcome(s)**

Current secondary outcome measure as of 15/12/2024:

1. Cumulative incidence of pT3 at radical prostatectomy specimens
2. Cumulative incidence of metastasis (will be assessed after each follow-up examination)
3. Cumulative number of treatments with curative intent (mainly radical prostatectomies or local radiotherapy)
4. Cumulative incidence of switch to watchful waiting
5. Prostate cancer mortality

6. Quality of life (will be assessed from questionnaires at baseline and every 2 years)

7. Costs

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3. Cumulative number of treatments with curative intent (mainly radical prostatectomies or local radiotherapy)
4. Cumulative incidence of switch to watchful waiting
5. Quality of life (will be assessed from questionnaires at baseline and every 2 years)
6. Costs

The first analysis for secondary endpoints will be performed 1 year after inclusion of the last patient.

### **Completion date**

31/12/2040

## **Eligibility**

### **Key inclusion criteria**

The inclusion criteria are:

1. Recently (within 12 months) diagnosed adenocarcinoma of the prostate
2. Tumour stage  $\leq$  T2a, NX, M0 (former MX)
3. PSA  $<15$  ng/ml, PSA density  $\leq 0,2$  ng/ml/cc
4. Gleason pattern 3+3=6 (any number of cores, any cancer involvement) or Gleason pattern 3+4=7 ( $<3$  cores (or  $<30$  % of cores if more than ten cores are taken),  $<10$  mm cancer in one core)
5. Life expectancy  $>10$  years with no upper age limit
6. Candidate for curative treatment if progression occurs
7. Signed written informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Male

### **Total final enrolment**

2009

### **Key exclusion criteria**

Participants not fulfilling the inclusion criteria

**Date of first enrolment**

01/10/2016

**Date of final enrolment**

30/09/2024

## **Locations**

**Countries of recruitment**

United Kingdom

England

Denmark

Finland

Norway

Sweden

**Study participating centre**

**Akademiska Hospital**

Uppsala

Sweden

SE-752 37

**Study participating centre**

**Sahlgrenska University Hospital**

Göteborg

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SE-413 45

**Study participating centre**

**Örebro University Hospital**

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SE-701 85

**Study participating centre**

**Linköping University Hospital**

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SE-581 85

**Study participating centre**  
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Helsinki  
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SW3 6JJ

**Study participating centre**  
**King's College Hospital**  
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SE5 9RS

**Study participating centre**  
**Umeå University Hospital**  
Umeå  
Sweden  
SE-901 85

**Study participating centre**  
**Sundsvall Hospital**  
Sundsvall  
Sweden  
SE-851 86

**Study participating centre**  
**Sunderby Hospital**  
Luleå  
Sweden  
SE-971 80



**Study participating centre**  
**Växjö Hospital**  
Växjö  
Sweden  
SE-351 85

**Study participating centre**  
**St Olavs Hospital**  
Trondheim  
Norway  
NO-7006

**Study participating centre**  
**Vestfold Hospital**  
Tønsberg  
Norway  
NO-3116

**Study participating centre**  
**Ålesund Hospital**  
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NO-6026

**Study participating centre**  
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CR7 7YE

## Sponsor information

**Organisation**  
Uppsala University

**ROR**  
<https://ror.org/048a87296>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Cancerfonden

**Alternative Name(s)**  
Swedish Cancer Society

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
Sweden

**Funder Name**

Svenska Forskningsrådet Formas

**Alternative Name(s)**

Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning, Swedish Research Council Formas, Formas

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Sweden

**Funder Name**

Nordic Cancer Union

## Results and Publications

**Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	22/08/2019	21/09/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes