ISRCTN64891728 https://doi.org/10.1186/ISRCTN64891728

A Swedish trial comparing two different follow-up schedules for patients with low-risk prostate cancer on active surveillance with selective, delayed treatment

Submission date
23/12/2010

Recruitment status
No longer recruiting

Registration date
17/02/2011

Overall study status
Completed

Last Edited
01/04/2016

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The prostate is a small gland in the pelvis found only in men. 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). The most commonly used tests for prostate cancer are a blood test (the PSA test), a physical examination of the prostate (digital rectal examination), and taking a small sample of tissue from the prostate (a biopsy). The aim of this study is to compare two different follow-up schedules for patients with low-risk prostate cancer on active surveillance with selective, delayed treatment.

Who can participate?
Men aged 50 to 75 who have been diagnosed with low-risk, localised prostate cancer in the last 6 months.

What does the study involve?
Participants are randomly allocated to one of two groups. One group undergoes a standard set of prostate biopsies with standard follow-up consisting of PSA testing every 3 months for 2 years, then every 6 months; digital rectal examination every 6 months for 2 years, then annually; and repeat standard biopsies every 24 months. The other group undergoes a more extensive set of biopsies with less intensive follow-up consisting of PSA testing every 6 months for 2 years, than annually; digital rectal examination annually; and no repeat biopsies unless needed. Participants are followed up for up to 15 years to assess how many go on to undergo treatment for prostate cancer.

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

Where is the study run from?
Lund University (Sweden)

When is the study starting and how long is it expected to run for?
February 2011 to December 2016

Who is funding the study?
1. Stig and Ragna Gorthon's Research Foundation (Sweden)
2. Örebro läns landstings särfond nr 5 (Sweden)
3. Gunnar Nilsson's Research Foundation (Sweden)
4. The Swedish Cancer Foundation (Sweden)

Who is the main contact?
Prof Ola Bratt
ola.bratt@skane.se

Contact information

Type(s)
Scientific

Contact name
Prof Ola Bratt

Contact details
Department of Urology
Lund University
Helsingborg Hospital
Helsingborg
Sweden
SE - 251 87
+46 (0)42 406 1000
ola.bratt@skane.se

Additional identifiers

Protocol serial number
2.0

Study information

Scientific Title
A Swedish randomised, multicentre, controlled trial comparing two different follow-up schedules for patients with low-risk, localised prostate cancer on active surveillance with selective, delayed intervention with curative intent

Acronym
SAMS-FU

Study objectives
The proportion of patients with low-risk prostate cancer planned for active surveillance that receive active therapy with curative intent within 5 years will not be different with an extensive,

initial re-biopsy and less intensive follow-up, including no further scheduled sets of prostate biopsies, than with standard initial re-biopsy and follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board at Lund University, 05/12/2010, ref: EPN 2010/598

Study design
Prospective multicentre randomised controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Localised prostate cancer

Interventions
Randomisation (1:1) within 6 months from diagnosis of prostate cancer, either to a standard set of prostate biopsies (9-16 cores depending on prostate volume) with standard follow-up (see below), or a more extensive set of biopsies (experimental arm, 15-26 cores depending on prostate volume) with less intensive follow-up.

Standard follow-up: PSA every 3 months for 2 years, then every 6 months; digital rectal examination every 6 months for 2 years, then annually; repeat standard biopsies every 24 months.

Follow-up in the experimental arm: PSA every 6 months for 2 years, than annually; digital rectal examination annually; no repeat biopsies unless any criterion for therapy is fulfilled, but no therapy initiated.

Patients will be followed prospectively for 5 years for the primary end-point and up to 15 years for the secondary end-points.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Active therapy for prostate cancer with curative intent within 5 years from diagnosis.
2. The first analysis for the primary end-point will be performed 1 year after inclusion of the last patient.
3. The second and final analysis will be performed 5 years after inclusion of the last patient.

Key secondary outcome(s))

1. The first analysis for secondary end-points will be performed after inclusion of the last patient. Subsequent analyses will be performed 5 and 10 years after inclusion of the last patient.
2. Detection of more extensive or less differentiated cancer in repeat biopsy
3. Therapy for prostate cancer with curative intent after more than 5 years from diagnosis
4. Recurrence following therapy with curative intent
5. Tumour characteristics in specimens from radical prostatectomy
6. Therapy for prostate cancer with non-curative intent
7. Change of strategy to expectancy without curative intent
8. Symptoms of prostate cancer and side-effects of treatment
9. Quality of life
10. Development of distant metastases
11. Death from prostate cancer
12. Death from other causes

Completion date
30/12/2016

Eligibility

Key inclusion criteria
1. Males aged 50 to 75 years
2. Expected remaining life-time of more than 10 years
3. Diagnosis of prostate cancer within the previous 6 months
4. Local therapy with curative intent is planned to be given if progression during follow-up
5. The patient has understood the concept of active surveillance and signed informed consent
6. Prostate specific antigen (PSA) less than 10 µg/l
7. PSA density less than 0.2 µg/l/cc
8. PSA free to total ratio greater than or equal to 0.1 (10%)
9. PSA-DT (doubling time) greater than 3 years during the last 2 years (if PSA-history available)
10. PSA increase of less than 2 µg/l within the last 2 years (if PSA-history available)
11. Tumour stage T1c or T2a (UICC 2002)
12. Prostate volume less than 90 cc
13. Gleason score less than or equal to 6 with no grade 4 or 5
14. Peripheral zone prostate cancer diagnosed with a set of biopsies including 6 - 12 cores
15. Less than or equal to 25% of cores with cancer
16. Less than or equal to 4 mm cancer in any one biopsy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
Male

Key exclusion criteria

1. Cancer in prostate biopsy cores sampling exclusively the anterior parts of the gland
2. Cancer diagnosed at TUR-P
3. Evidence of metastatic cancer
4. Any previous therapy for prostate cancer
5. Treatment with 5-alpha-reductase inhibitors during the previous 12 months
6. Additional sets of prostate biopsies within the previous 12 months
7. Recurrent urinary tract infection or bacterial prostatitis
8. Ano-rectal disease interfering with digital rectal examination or ultrasound
9. Any other disease or circumstance that may interfere will study-related procedures

Date of first enrolment
15/02/2011

Date of final enrolment
30/12/2016

Locations

Countries of recruitment
Sweden

Study participating centre
Lund University
Helsingborg
Sweden
SE - 251 87

Sponsor information

Organisation
The Swedish National Prostate Cancer Register (Sweden)

Funder(s)

Funder type
Research organisation

Funder Name
Stig and Ragna Gorthons Research Foundation (Sweden)

Funder Name
Örebro läns landstings särfond nr 5 (Sweden)

Funder Name
Gunnar Nilssons Research Foundation (Sweden)

Funder Name
Swedish Cancer Foundation (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes