

# A randomised trial comparing hormonal treatment versus combination of hormonal treatment and radiotherapy in locally advanced prostate cancer

<b>Submission date</b> 29/05/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 13/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/04/2009	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
Version 1996 01 09

## Study information

**Scientific Title**

Randomised trial of locally advanced/aggressive prostatic cancer: T3 diff grad 1-3, T1b - T2 diff grad 2-3 (optional), NO, MO antiandrogen treatment with or without radiotherapy

**Acronym**

SPCG-7/SFUO-3

**Study objectives**

To evaluate if the addition of radiotherapy improves the outcome in hormonally-treated, locally advanced/aggressive, node-negative and non-metastasised prostatic cancer.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received from Umeå University, Medical Faculty Ethical Committee in 1995 (ref: paragraph 247/95; diary no. 95-179).

**Study design**

A randomised open, comparative, parallel design trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Local or locally advanced prostate cancer, pN0, M0

**Interventions**

After randomisation all patients were treated with total androgen blockade (TAB) with an LHRH-agonist (Procren Depot; Abbott), for three months in combination with an oral anti-androgen (AA) Eulexin (Schering-Plough) 250 mg x 3. Thereafter all patients continued on the anti-androgen alone, T Eulexin 250 mg x 3 daily, continuously until progression. After three months patients in the Radiotherapy+Hormone arm started radiotherapy whereas patients in the Hormone-only arm had no local treatment. Minimal radiation dose to the prostate will be 70 Gy and the seminal vesicles will be included up to a minimum dose of 50 Gy.

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Leuprolide (Procren Depot), flutamide (Eulexin)

**Primary outcome(s)**

To evaluate if cause-specific seven-year survival can be improved in patients treated with a combination of radiotherapy and anti-androgen as compared to anti-androgen therapy only.

Primary and secondary endpoints were planned to be analysed after seven years.

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

1. To evaluate:
  - 1.1. Time to biochemical progression (PSA)
  - 1.2. Time to symptoms related to local progression
  - 1.3. Time to symptoms related to distant progression
2. To evaluate quality of life (QOL) with special focus on sexual function, urinary and gastrointestinal morbidity

Primary and secondary endpoints were planned to be analysed after seven years.

### **Completion date**

30/12/2002

## **Eligibility**

### **Key inclusion criteria**

1. Men less than 76 years of age and, as judged by the doctor, a life expectancy of less than 10 years (except for cancer) at time of randomisation with performance status World Health Organization (WHO) 0 - 2
2. Patients with histologically/cytologically verified prostatic cancer
3. Patients with prostatic cancer of clinical category T1b-T2; G2-G3 and T3; G1-G3 according to the TNM classification system of 1992. Inclusion of patients with T1b-T2; G3 and T2; G2 is optional.
4. The patients should have no evidence of metastases by clinical investigation, bone scan or pulmonary x-ray
5. Patients should be lymph node negative
6. Patients should be suitable for radiotherapy and anti-androgen treatment

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Male

### **Key exclusion criteria**

1. Patients who earlier have undergone any other treatment against prostatic cancer except transurethral resection of the prostate (TUR-P)
2. Patients with a prostate specific antigen (PSA) greater than 70 ng/ml
3. Patients unable to cooperate or suffering from any other form of disease that would interfere with the planned treatment (e.g. colitis)
4. Liver function that would interfere with the anti-androgen treatment (a bilirubin and/or alanine aminotransferase [ALAT] value above the upper normal limit)

5. Patients with previous diagnosis of other malignant disease. Exceptions could be made for basal cell carcinoma of the skin or progression free survival at least 10 years after any previous tumour (this requires discussion with the study co-ordinator).

**Date of first enrolment**

27/02/1996

**Date of final enrolment**

30/12/2002

## **Locations**

**Countries of recruitment**

Denmark

Norway

Sweden

**Study participating centre**

**Department of Radiation Sciences, Oncology**

Umeå

Sweden

90185

## **Sponsor information**

**Organisation**

Scandinavian Prostate Cancer Group (SPCG) (Sweden)

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Scandinavian Prostate Cancer Group (SPCG) (Sweden) - after receiving an unrestricted grant from Schering-Plough Inc. and Abbott Scandinavia Inc.

**Funder Name**

## 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?
<a href="#">Results article</a>	results	24/01/2009		Yes	No
<a href="#">Results article</a>	four-year follow-up results	01/04/2009		Yes	No