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The incidence of residual prostate cancer in patients included in a randomised trial comparing hormonal treatment versus combination of hormonal treatment and radiotherapy in locally advanced prostate cancer

Submission date 31/08/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 28/09/2009	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 28/09/2009	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Post-treatment prostatic biopsies after anti-androgen treatment with or without radiotherapy of locally advanced prostatic cancer: side study of the SPCG-7/SFUO-3 randomised trial

Study objectives
The incidence of residual local tumour in prostatic biopsies from patients with locally advanced prostatic cancer following 3 years (and 6 months) hormonal treatment with flutamide, is not statistically different from the incidence seen in patients treated with radiotherapy and flutamide.

Please note that this is a side-study to a previously registered trial, which can be found under ISRCTN01534787 - "A randomised trial comparing hormonal treatment versus combination of hormonal treatment and radiotherapy in locally advanced prostate cancer [SPCG-7/SFUO-3 trial]" (http://www.controlled-trials.com/ISRCTN01534787).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Committee for Medical and Health Research Ethics of Middle-Norway approved on the 15th August 2000 (ref: 112-2000)

Study design
Side-study to a randomised open comparative parallel-design trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (only in Swedish and Norwegian)

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 and 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.

Prostate biopsies should be taken at the 3 year (and 6 months) follow up visit.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Flutamide, Procren Depot, T Eulexin

Primary outcome measure
To compare the incidence of residual local tumour following hormonal treatment with the analogue incidence rate after the combination of hormonal treatment and radiotherapy. The incidence of residual prostate cancer was measured by post-treatment prostate biopsies performed 3 years plus/minus 6 months from randomisation in the SPCG-7/SFUO-3 trial.

Secondary outcome measures
1. To study the prognostic implication of post-treatment residual tumour in patients included in SPCG-7. The prognostic implications of residual cancer were measured with respect to the following events:
1.1. PSA-recurrence
1.2. Local recurrence (clinical)
1.3. Distant recurrence (metastasis)
1.4. Death
These were measured as follows: All patients were followed by the the treating physician every 6 months from randomisation in the SPCG-7/SFUO-3 trial, and data with respect to these events was registered in the SPCG-7/SFUO-3 case report file (CRF) on every visit. In patients who had died, the cause of death was registered in the CRF. By the end of February 2008 survival status was controlled against the nation-wide population registries in Sweden and Norway.
2. To obtain a storage of post-treatment biopsies for the possibility of further characterisation of residing tumour cells by means of immunohistochemical staining methods for potential prognostic markers. A storage of post-treatment prostate biopsies for the possibility of further characterisation of residing tumour cells was obtained at the time of biopsy (3 years plus/minus 6 months from randomisation in the SPCG-7/SFUO-3 trial).

Overall study start date
01/03/2001

Completion date
31/10/2005

Eligibility

Key inclusion criteria
1. Patients must have been included in the SPCG-7/SFUO-3 study with the following inclusion criteria:
1.1. 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
1.2. Patients with histologically/cytologically verified prostatic cancer
1.3. 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.
1.4. The patients should have no evidence of metastases by clinical investigation, bone scan or pulmonary x-ray
1.5. Patients should be lymph node negative
1.6. Patients should be suitable for radiotherapy and anti-androgen treatment
2. Written patient informed consent
3. WHO performance status (Zubrod) 0 - 1
4. No medical hazard connected with the previous or the planned biopsy-procedure

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
200 patients

Key exclusion criteria
1. Patient refusal
2. Medical hazard during previous prostatic biopsy procedures
3. Medical hazard expected during the planned biopsy procedure
4. Serious urine outlet-problems or risk of infections or haemorrhage

Date of first enrolment
01/03/2001

Date of final enrolment
31/10/2005

Locations

Countries of recruitment
Norway

Sweden

Study participating centre
St. Olavs Hospital
Trondheim
Norway
7006

Sponsor information

Organisation
Scandinavian Prostate Cancer Group (SPCG) (Sweden)

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Sponsor type
Research organisation

Website
http://www.spcg.no/

Funder(s)

Funder type
Charity

Funder Name
The Nordic Cancer Union (Norway)

Funder Name
The Norwegian Cancer Society (Norway)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration