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

Submission date 29/05/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/06/2008	**Overall study status** Completed	
Last Edited 08/04/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Anders Widmark

Contact details
Department of Radiation Sciences, Oncology
Umeå University, Hospital
Umeå
Sweden
90185
Anders.Widmark@onkologi.umu.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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, Norwegian and Danish)

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 measure
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.

Secondary outcome measures
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.

Overall study start date
27/02/1996

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

Age group
Adult

Sex
Male

Target number of participants
Initilly 660, later enlarged to 880, due to fewer events than expected

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)

Sponsor details
c/o P.O.Hedlund
Skogsstigen 22
131 42 Nacka
Stockholm
Sweden
103 42

Sponsor type
Research organisation

Website
http://www.spcg.se

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
Nordic Cancer Union (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/01/2009		Yes	No
Results article	four-year follow-up results	01/04/2009		Yes	No