

Title of trial	An open randomized phase III trial of six cycles of docetaxel versus surveillance after radical prostatectomy in high grade prostate cancer patients with margin positive pT2 or pT3 tumours. "AdPro" (SPCG 12)
Trial Coordinators	Göran Ahlgren, M.D., Ph.D., Dept. of Urology, University Hospital of Malmö, S-205 02 Malmö, Sweden and Gunnar Westman, M.D., Ph.D., Dept. of Oncology, University Hospital of Malmö, S-205 02 Malmö, Sweden
Trial period	Planned duration of the trial: 8 years Planned enrolment duration: 3 years Start enrolment date: October 2005 Stop enrolment date: October 2008 End of trial: 2013 Final Trial Report: 2014
Objectives	1) PSA progression. 2) PSA doubling time, Quality of Life (QoL), Metastasis free survival, Overall survival.
Methodology	Phase III, open label, non-blinded, randomised, multicentre and multinational trial.
Number of patients	396
Main criteria for inclusion	<ul style="list-style-type: none"> <li>• Men &gt; 18 and ≤70 years of age.</li> <li>• WHO/ECOG performance status 0 – 1.</li> <li>• Histologically proven adenocarcinoma of the prostate.</li> <li>• Either of the following: <ul style="list-style-type: none"> <li>○ pT2 with Gleason score 4+3 or 8-10 and positive margins in the radical prostatectomy specimen or</li> <li>○ any pT3 tumour with Gleason score 4+3 or higher.</li> </ul> </li> <li>• If pre-operative PSA ≥ 10.0 ng/ml, lymph node dissection should be performed.</li> <li>• Post-operative PSA ≤ 0.5 ng/ml.</li> <li>• Adequate haematological-, liver- and kidney function.</li> <li>• Negative bone scan prior to trial start.</li> <li>• Written informed consent.</li> </ul>
Main criteria for exclusion	<ul style="list-style-type: none"> <li>• M+</li> <li>• N+ (Known positive lymph nodes at histological examination).</li> <li>• Patients with a history of previous malignant disease. Exceptions should be made for basal cell carcinoma (BCC) and squamous cell carcinoma of the skin. Exceptions should also be made for curatively treated malignant disease, which has been disease free for the past five years.</li> <li>• Previous hormonal manipulation (e.g. LHRH analogues and/or antiandrogens) affecting prostate cancer cells.</li> <li>• Previous radiotherapy to pelvic region.</li> <li>• Previous chemotherapy.</li> <li>• Systemic corticosteroids within 6 months prior to randomisation.</li> <li>• Unstable cardiovascular disease within 6 months prior to randomisation.</li> <li>• Active untreated infectious disease.</li> </ul>

	<ul style="list-style-type: none"> <li>• Active gastric ulcer.</li> <li>• Known hypersensitivity to Polysorbate 80.</li> <li>• Other serious illness or medical condition.</li> <li>• Symptomatic peripheral neuropathy <math>\geq</math> CTCAE grade 2.</li> <li>• Patients who by altered physical or psychological state not are able to co-operate or participate in the trial.</li> </ul>
Treatment	Docetaxel 75 mg/m <sup>2</sup> i.v. in 60 minutes on day 1 or surveillance. One cycle is 21 days.
Duration of trial and follow-up	Docetaxel will be given every three weeks for six cycles. Follow-up is planned until 50% of patients in the surveillance arm have a PSA progression or maximum of 5 years. The PSA difference between the arms is estimated to be 15% at this time.