

**Results of a randomized trial comparing short vs. protracted neoadjuvant hormonal therapy (NHT) prior to radiation therapy (RT) of localized prostate cancer**

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**Background:** Adjuvant hormonal therapy improves survival of selected prostate cancer patients. However, there are few trials that address the variables of adjuvant hormones. This randomized trial compared short (4 months) vs. long (8 months) NHT prior to RT.

**Methods:** From 1997–2001, 276 pts. enrolled of whom 256 are analysed. Stratification risk factors were PSA >20, Gleason score >7, and >T3. The intermediate-risk stratum had one factor, the high-risk stratum had >2 factors. Staging included bone scan, and CT to exclude nodal involvement. NHT consisted of monthly LHRH agonist (triptorelin – Decapeptyl) and Flutamide 250 mg 3 times daily (Drogenil). Localized RT was 66 Gy in a minority and 92% got 70 Gy using 3-D to prostate and vesicles. The primary endpoint was PSA relapse-free survival (P-RFS), calculated by the ASTRO method from the date of commencement of NHT.

**Results:** On multivariate analysis the Gleason score and log of the initial PSA were significant predictors of P-RFS.

	4 months	8 months
Overall	N = 128	N = 127
5 year P-RFS	45%	49%
Intermediate risk	N = 67	N = 66
5 year P-RFS	51%	51%
High risk	N = 62	N = 61
5 year P-RFS	46%	41%

All p values = NS.

**Conclusions:** For these intermediate and high risk patients the overall PSA relapse free survival is low, but comparable to the relevant literature. However, the ASTRO method of calling a PSA relapse overestimates true relapse and may have undermined the interpretation of this trial. Most patients had salvage hormones at relapse and did not have a chance to develop the more appropriate Phoenix failure criteria.