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Preliminary results of a randomised trial comparing short vs. protracted neoadjuvant hormonal therapy (NHT) prior to radiation therapy (RT) of localized prostate cancer. (Irish Clinical Oncology Research Group Protocol # 97-01)

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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 randomised 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 $\geq T3$. 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 (Drogenil[®]) 250mg 3 times daily. Localized RT was 66Gy in a minority and 92% got 70Gy using 3-D to prostate and vesicles. The primary endpoint was PSA relapse-free survival (P-RFS), calculated by the RTOG method from the date of the last NHT injection to avoid bias.

Results: On multivariate analysis the log of the initial PSA and the risk stratum were significant. The median follow-up was 35 months. Median P-RFS has not yet been reached so the time to 70% P-RFS is reported.

	4 months arm	8 months arm
Intermediate-risk		
Time to 70% P-RFS	48 months	47 months
Projected 5 year P-RFS	67%	64%
High-risk		
Time to 70% P-RFS	23 months	32 months
Projected 5 year P-RFS	53%	66%

Conclusions: The trend in favour of 8 months NHT for high-risk patients is not significant. Further follow-up will be required to determine if the duration of NHT influences the primary endpoint.