DEGARELIX VERSUS LUTEINISING HORMONE-RELEASING HORMONE (LHRH) AGONISTS: OUTCOMES FROM POOLED PATIENT DATA FROM MULTIPLE CLINICAL TRIALS

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Background: LHRH agonists and the gonadotrophin releasing hormone antagonist, degarelix, are used to treat men with hormone-dependent advanced prostate cancer. Degarelix has a distinct mechanism of action and differences exist in disease control between these agents. Analysis of pooled data from phase III comparative trials allows further investigation of treatment outcomes.

Materials and methods: Individual patient data were pooled from up to 6 prospective, comparative randomized trials (sponsored by Ferring Pharmaceuticals) of degarelix vs. LHRH agonists (n=2328). Events were analyzed using Kaplan-Meier plots, a log-rank test for homogeneity and the Cox proportional hazard model.

Results: Baseline characteristics including age and cardiovascular disease (CVD) history were balanced. 1491 patients received degarelix and 837 a LHRH agonist. Overall probability of any urinary tract adverse event (AE) (p<0.001), urinary tract infection (p=0.004) and joint related signs and symptoms (p=0.041) were significantly lower in men receiving degarelix. In patients with CVD history, risk of a subsequent CV event or death was significantly lower in degarelix patients (HR=0.44, 95% CI, 0.26–0.74; p=0.002). The risk of a serious CV event was also significantly lower in patients with CVD history receiving degarelix (p=0.0086). When adjusted for baseline factors, mortality was lower in patients treated with degarelix (HR=0.47, 95% CI 0.25–0.90; p=0.023).

Conclusion: These analyses demonstrates that, during the first year of treatment, men treated with degarelix had a reduced risk of disease-related AEs. There was also a lower risk of death, likely due to the higher incidence of CV events in LHRH agonist patients.