However, at 70% the 5-year survival for the whole population is of great interest.

Follow up period and an estimated 5-year survival rate equal to 70% (95%CI: 59-79) in both arms. (p=0.81). No differences were observed on survival rates (p=0.94) with a total of 27 pts (both arms) who died during their follow-up. Patients (pts) with hormone receptor positive (HR+) tumors received hormonotherapy. Pts were to be followed for 3 years and 5-year disease-free survival (DFS) rates were similar in both arms, 63.0% (95%CI: 51.9-72.2) and 55.5% (95%CI: 44.9-66.1) for ArmA and ArmB respectively. 1.000 pts were evaluable for response and survival analysis and 1.000 pts were evaluable for toxicity analysis.

Patients with metastatic disease (20%) were excluded from the DFS analysis. The number of pts with unknown OS was 2 (ArmA) and 4 (ArmB). The median follow-up for both arms was 59.8 months (range 1-108) and 59.9 months (range 1-108) respectively. The statistical analysis was performed using a Cox model with a non-parametric Kaplan-Meier estimate and the log-rank test: p<0.05 was considered to be significant. The α level was set at 0.05 (2-tailed).

This study is one of the largest randomized studies in inflammatory breast cancer (Pegase 02) and one of the few with a 3-year DFS rate assessment. The results confirm the hypothesis of the superiority of the combination of EC-HD and intensive pre-operative ERIC-C in terms of the main endpoints (DFS and survival).

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