

# COMPARISONS BETWEEN GROUP SEQUENTIAL AND ADAPTIVE DESIGNS IN A REAL EXAMPLE

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The merits of group sequential designs and adaptive designs have been presented in the literature. To evaluate the impact of various options of two-stage group sequential and adaptive designs on a real example, a randomized two-arm clinical trial in postmenopausal patients with breast cancer (European Journal of Cancer 33:1017-1024, 1997) is retrospectively redesigned for a different endpoint and different hypothesized effect sizes. The only adaptation considered in the adaptive designs is sample size. The actually observed data are reanalyzed according to the new designs. Conclusions and final sample sizes of various designs are compared. As expected, the conclusions from comparable group sequential and adaptive designs are not always the same. When the actual effect size is somewhat smaller than the hypothesized value, the group sequential design fails to reject the null hypothesis. However, the adaptive design with an enlarged stage-2 sample size could result in rejection of the null hypothesis. Such adaptation makes the final sample sizes of adaptive designs generally larger than that of group sequential designs.