BREAST CANCER

High-dose fulvestrant is a safe and effective therapy for breast cancer

Fulvestrant is an estrogen-receptor targeting therapy that is used for the treatment of advanced-stage breast cancer in postmenopausal women with endocrine-sensitive cancer. The current approved dose is 250 mg but observational and phase II evidence indicated that a higher dose might be more effective.

The observations led to a hypothesis-driven phase III, randomized clinical trial conducted by the Comparison of Faslodex in Recurrent or Metastatic Breast Cancer (CONFIRM) investigators. They assessed two doses of fulvestrant (250 mg and 500 mg) in 736 women with advanced disease who had progressed on first-line endocrine therapy.

The primary end point of the present study was progression-free survival, which was significantly improved in the patients receiving the high-dose fulvestrant compared with the low-dose group; 6.5 months and 5.5 months, respectively. This improvement was equivalent to a 20% reduction in the risk of progression.

An important aspect of this trial was the analysis of adverse events and the quality of life of the participants. No significant difference in these areas was observed when comparing the two groups.

The study did not reveal a significant difference in overall survival despite a trend towards an improvement in the high-dose group. A survival analysis will be completed on the mature data in 2011.

The authors recommend in their article that "fulvestrant 500 mg... should replace the currently approved 250-mg schedule in current medical practice."

Rebecca Kirk

Original article Di Leo, A. *et al*. Results of the CONFIRM phase III trial comparing fulvestrant 250 mg with fulvestrant 500 mg in postmenopausal women with estrogen receptor-positive advanced breast cancer. *J. Clin. Oncol*. **28**, 4594–4600 (2010)