Evaluation of trastuzumab without chemotherapy as a postoperative adjuvant therapy in HER2 positive elderly breast cancer patients: Randomized controlled trial (RESPECT [N-SAS BC07])

M. Sawaki1, H. Iwata2, M. Kashiwaba1, N. Taira3, N. Tokudome1, T. Nakayama6, H. Bando4, T. Mizuno5, S. Murakami4, Y. Yamamoto5, Yukari Uemura6 and Yasuo Hashi7
1Clinical Oncology and Chemotherapy, Nippon Medical School Graduate School of Medicine; 2Anesthesia, Surgery, Cancer Center Joetsu, Joetsu City, Niigata Prefecture; 3Medical Oncology, Department of Medical Oncology, Cancer Institute Hospital of Japanese Foundation for Cancer Research, Tokyo; 4Innis and Endo Surgical, Osaka University; 5Tokushukai Hospital, Utsunomiya; 6Medical Oncology, Meiji University Graduate School of Medicine; 7Surgery, Hiroshima City Hospital, Hiroshima; 8Department of Breast and Endocrine Surgery, Graduate School of Medical Sciences, Kumamoto University, Kumamoto, Japan; 9Biostatistics, Schist of Public Health, University of Tokyo, Tokyo, Japan.

Abstract

This randomized trial was conducted in vibratorially between HER2 positive breast cancer patients (HER2+BC) to determine whether trastuzumab chemotherapy is more effective than trastuzumab monotherapy chemotherapy in elderly breast cancer patients with HER2 overexpression.

Materials and Methods

Elderly breast cancer patients with histologically confirmed operable breast cancer and HER2 positive, who were classified as Stage I-III were randomized into two arms: HER2 + chemotherapy and monotherapy arm. A total of 200 patients were randomized to the two arms. Patients were randomly assigned to receive trastuzumab (8 mg/kg loading dose, and 6 mg/kg q3w) with or without chemotherapy. The relationship of trastuzumab monotherapy with chemotherapy was investigated in a randomized controlled trial in 50 elderly breast cancer patients.

Results

In the intention-to-treat analysis, the overall survival rate was significantly higher in the HER2 + chemotherapy group compared to the HER2 monotherapy group. The results indicated that trastuzumab chemotherapy was more effective than trastuzumab monotherapy in elderly breast cancer patients with HER2 positive.

Conclusions

This randomized controlled trial demonstrated that trastuzumab chemotherapy is more effective than trastuzumab monotherapy chemotherapy in elderly breast cancer patients with HER2 overexpression.