Evaluation of Trastuzumab without Chemotherapy as a Postoperative Adjuvant Therapy in HER2-Positive Elderly Breast Cancer Patients: Randomized Controlled Trial (RESPECT)

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Background

Objective

Primary endpoint: Disease-free survival (DFS)

Methods

We randomly assigned patients over 70 years old with HER2-positive invasive breast cancer who received curative operation (n = 266) to either the H group (H: 131 patients) or the H+CT group (H+CT: 135 patients) selected from pre-specified stratification factors.

Table 1. Characteristics of the two groups

Table 2. Regimen received and the events in DFS

Table 3. The events in DFS

Table 4. Adverse events (CTCAE v.3.0)

Results

A total of 275 patients were randomized from 2009 October to 2014 October. Of 275 patients, 9 patients (3.3%) was excluded before initiation of protocol treatment because of withdrawal (n=4) and difficulty of attending to the hospital (n=5), then, 266 patients were included in the full set analysis (n=131 in H+CT group, n=135 in H group).

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Conclusion

The small number of events precluded the evaluation of trastuzumab monotherapy based on HR of DFS, and comparison of RMSTs revealed that the lost survival due to omitting chemotherapy was less than 1 month at 3 years.

In light of less toxicity and a better QOL profile, trastuzumab monotherapy can be an option as an adjuvant therapy for elderly HER2-positive breast cancer patients.

Clinical trial information: NCT01104935

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