

TRASTUZUMAB AND DOCETAXEL COMBINATION THERAPY COMPARED TO DOCETAXEL MONOTHERAPY IN HER2-POSITIVE STAGE IV METASTATIC BREAST CANCER – AN OPEN LABELLED RANDOMIZED STUDY

ABSTRACT

Background: Pre-clinical and clinical studies indicate that a combination of docetaxel and trastuzumab may effectively treat patients with human epidermal growth factor receptor-2 (HER-2) overexpressing metastatic breast cancer. Therefore, this study was designed to compare the efficacy, safety and tolerability of trastuzumab plus docetaxel and docetaxel monotherapy in HER-2 Positive Metastatic Breast Cancer patients.

Methods: A total of 40 patients were randomly assigned to two groups. Twenty patients (Group 1) were assigned into six cycles of docetaxel 75 mg/m² every 21 days with trastuzumab 8 mg/kg loading dose followed by 6 mg/kg weekly and Group 2, twenty patients were assigned into six cycles of docetaxel 75 mg/m² every 21 days.

Results: Objective responses of Trastuzumab with docetaxel combination and docetaxel monotherapy were found to be similar without any significant difference between the study groups. Subjective responses after sixth cycle were found to be similar in both the groups. Side-effects were similar in both the study groups. The most common haematological toxicity was leukopenia. Non-Haematological toxicities reported were alopecia, peripheral neuropathy, myalgia/arthralgia and nail discolouration and they were almost equal in both the study groups.

Conclusion: Trastuzumab with docetaxel combination was certainly a promising combination for metastatic breast cancer in patients with HER-2-overexpression. Further long term studies regarding overall survival, overall response rate and time to progression would be needed to confirm the effectiveness of this combination over docetaxel monotherapy in the metastatic setting.

Key words: Metastatic breast cancer, HER-2, trastuzumab, docetaxel