

MESOTHELIOMA

1960 STELLAR: Final updated results of a phase II trial of TTFields with chemotherapy for unresectable malignant pleural mesothelioma

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Background: Tumor Treating Fields (TTFields), an anti-mitotic, regional treatment approved for glioblastoma utilizes low intensity, alternating electric fields delivered non-invasively to the tumor using a portable medical device. In-vitro, human mesothelioma cells were highly susceptible to TTFields.

Methods: The trial accrued 80 patients with unresectable, previously untreated mesothelioma. Patients were treated with continuous 150 kHz TTFields (>18h/day) in combination with pemetrexed and cisplatin or carboplatin. Inclusion criteria included ECOG PS of 0-1 and pathologically proven mesothelioma. The primary endpoint was overall survival (OS). A visual analog scale was used to assess EOCG performance status and cancer-related pain assessed until disease progression. The sample size provided 80% power with two-sided alpha of 0.05 to detect an increase in median OS of 5.5 months compared to historical controls (Vogelzang, JCO 2003).

Results: All 80 patients had a minimum follow up of 12 months. Median age was 67 (range 27-78), 84% were male and 44% (35 patients) had an ECOG PS of 1. 66% (53 patients) had epithelioid histology, similar to the Vogelzang study. Median OS was 18.2 months (95% CI 12.1-25.8) versus 12.1 months in the historical control. Median OS for epithelioid patients was 21.2 months (95% CI 13.2-25.8). ECOG score was stable during the first year of follow up. Median time to deterioration in performance status was 13.1 months. Average score of pain was lower compared to baseline during the first 7 months of the treatment and was higher later on the study, with a median time to a clinical significant 33% increase in pain of 8.4 months. No device-related serious adverse events (AEs) were reported. Expected TTFields-related dermatitis was reported in 46% (37 patients). Four patients (5%) had grade 3 dermatitis.

Conclusions: The study met primary endpoint of significant extension of overall survival in previously untreated mesothelioma patients. TTFields was not associated with a decrease in performance status or an increase in pain for the duration of TTFields use. TTFields in combination with chemotherapy is efficacious in malignant pleural mesothelioma compared to historical data.

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