Lung

Phase III Randomised Trial of Prophylactic Cranial Irradiation With or Without Hippocampus Avoidance in SCLC (NCT01780675)

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INTRODUCTION

To compare neurocognitive functioning in patients with small cell lung cancer (SCLC) who received prophylactic cranial irradiation (PCI) with or without hippocampus avoidance (HA).

METHODS

In a multicenter, randomised phase III trial (NCT01780675), patients with SCLC were randomised to standard PCI or HA-PCI of 25 Gy in 10 fractions. Neuropsychological tests were performed at baseline and 4.0, 8.0, 12, 18, and 24 months after PCI. The primary end point was total recall on the Hopkins Verbal Learning Test-Revised at four months; a decline of at least five points from baseline was considered a failure. Secondary end points included other cognitive outcomes, evaluation of the incidence, location of brain metastases, and overall survival.

RESULTS

From April 2013 to March 2018, a total of 168 patients were randomised. The median follow-up time was 26.6 months. In both treatment arms, 70% of the patients had limited disease and baseline characteristics were well balanced. Decline on the Hopkins Verbal Learning Test-Revised total recall score at four months was not significantly different between the arms: 29% of patients on PCI and 28% of patients on HA-PCI dropped greater than or equal to five points (p = 1.000). Performance on other cognitive tests measuring memory, executive function, attention, motor function, and processing speed did not change significantly different over time between the groups. The overall survival was not significantly different (p = 0.43). The cumulative incidence of brain metastases at two years was 20% (95% confidence interval: 12%-29%) for the PCI arm and 16% (95% confidence interval: 7%-24%) for the HA-PCI arm.

CONCLUSIONS

This randomised phase III trial did not find a lower probability of cognitive decline in patients with SCLC receiving HA-PCI compared with conventional PCI. No increase in brain metastases at two years was observed in the HA-PCI arm.