HIROSE-1: BNCT With an Accelerator-Based System and Borofalan(^{10}B) for Recurrent or Locally Advanced Head and Neck Cancer (JHN002): An Open-Label Phase II Trial

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Background: In the context of the development of a new widely available BNCT system, clinical trials to investigate the efficacy and safety of BNCT using an accelerator neutron irradiation system and ^{10}B-condensed boronophenylalanine (BPA) as a ^{10}B agent are urgently needed. Here we report a phase II nonrandomized trial exploring BNCT using an accelerator-based neutron generator (A-BNCT) with borofalan(^{10}B), which is the generic name of ^{10}B-BPA, for head and neck cancer.

Methods: In this open-label phase II trial of BNCT using an accelerator system with borofalan(^{10}B), patients with platinum-resistant recurrent squamous cell carcinoma of the head and neck (R-SCC-HN) or with recurrent/locally advanced non-squamous cell carcinoma of the head and neck (R/LA-nSCC-HN) were intravenously administered 200 mg/kg/h borofalan(^{10}B) for 2 h, followed by neutron irradiation with continuous infusion of 100 mg/kg/h. The irradiated dose for the tumor was determined passively as the mucosal maximum dose of 12 Gy-Eq. The primary endpoint was the objective response rate (ORR) determined.

Results: Eight R-SCC-HN and 13 R/LA-nSCC-HN patients were enrolled. All R-SCC-HN patients had prior radiotherapy with a dose of 65.5 Gy (range, 59.4–76.0 Gy). The ORR for all patients was 71.4%, and complete response / partial response were 50.0% / 25.0% in R-SCC-HN and 7.7% / 61.5% in R/LA-nSCC-HN. With a median follow-up of 24.2 months (interquartile range, 24.0–24.3 months), the 2-year overall survival for R-SCC-HN and R/LA-nSCC-HN were 58.3% and 100%, respectively. Frequently observed adverse events included alopecia (95.2%), nausea (81.0%), dysgeusia (71.4%), and parotitis (66.7%), and no grade 4 or 5 adverse events were observed.

Conclusion: These data suggest that BNCT using an accelerator system with borofalan(^{10}B) is a promising treatment option for patients with R-SCC-HN or R/LA-nSCC-HN.