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Poster Session

JCOG2002: A randomized phase III study of thoracic radiotherapy for extensive stage small cell lung cancer.

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Background: Consolidative thoracic radiotherapy (cTRT) has shown a marginal improvement in overall survival (OS) and progression-free survival (PFS) for extensive-stage small-cell cancer (ES-SCLC). Consequently, ASTRO and NCCN guidelines conditionally recommend the use of cTRT. Despite the recent establishment of anti-PD-L1 antibody (aPD-L1) combined with platinum-doublet chemotherapy as the standard first-line treatment for ES-SCLC, the impact of cTRT in the era of immunotherapy remains uncertain. **Methods:** The JCOG2002 study, a randomized, multicenter phase 3 trial, initiated in October 2021 to assess the superiority of additional cTRT in terms of OS for ES-SCLC following induction aPD-L1 plus platinum doublet chemotherapy. Eligibility patients must meet criteria for the first registration including ES-SCLC, no prior radiation or chemotherapy history, age 20 or older, ECOG performance status 0 or 1, and adequate organ function. Induction treatment involves atezolizumab + carboplatin + etoposide or durvalumab + cisplatin / carboplatin + etoposide. Responding patients proceed to the second registration, randomization (1:1 between 30 Gy in 10 fractions of cTRT plus aPD-L1 maintenance therapy and maintenance therapy only). The cTRT targets metastatic lymph nodes in stations #1-7 and ipsilateral stations #10-12 identified at diagnosis. The adjustment factors include response to induction treatment (CR/PR versus SD), presence of brain metastasis (yes versus no), participating institutions, and aPD-L1 type (atezolizumab versus durvalumab). The primary endpoint is OS, with secondary endpoints being PFS and safety. The study aims to enroll 240 randomized patients, with 330 in the first registration, providing 80 % power at a one-sided 5 % significance level to detect a hazard ratio of 0.69 with 3-year accrual period and 1-year follow-up. As of February 6, 2024, 239 patients initiated induction treatment, and 121 have been randomized. This trial is registered at Japan Registry of Clinical Trials as jRCTs031210393 (https://jrct.niph.go.jp/detail/jRCTs031210393). Clinical trial information: jRCTs031210393. Research Sponsor: Japan Agency for Medical Research and Development; 24ck0106866h0002; National Cancer Center Research and Development Fund; 2020-J-3, 2023-J-0.