TPS6118 **Poster Session**

A phase III randomized controlled trial comparing palliative stereotactic body radiotherapy vs. palliative standard radiotherapy in patients with advanced head and neck cancer (NCT06641791).

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Background: The optimal radiotherapy (RT) treatment regimen for patients with advanced head and neck cancer (AHNC) unsuitable to receive curative intent RT is undefined. Stereotactic body radiotherapy (SBRT) is a promising technique but rigorous multicentre evaluation is required prior to adoption. **Methods:** This is a Phase III randomized controlled trial comparing palliative SBRT to palliative standard RT (SRT) in participants with advanced mucosal, squamous cell head and neck cancer unable to tolerate curative intent RT. Key eligibility criteria: Unsuitable for curative intent therapy, no evidence of metastatic disease, stages TX or T0-T4/ N0-N3, geriatric 8 score [1] ≤14. Treatment arms: (Experimental) SBRT 4500 cGy/ 5fr (twice a week to primary and nodal GTV (BED_{10}85) OR 4000 cGy /5 fr twice a week if organs at risk (BED_{10}-72) versus (standard) 2400 cGy/ 3fr (day 0/7/21 (BED_{10}43) or 2500 cGy/ 5fr over 1 week (BED_{10}38). Primary objective: To compare OS between arms. Secondary objectives evaluate progression-free survival (PFS), locoregional failure-free survival, distant metastases-free survival, response rates, acute and long-term toxicity (CTCAE v5.0), treatment compliance, patient-reported outcomes (PRO-CTCAE, FACT-HN), resource utilization, and health utilities. Statistical design: The trial aims to enroll 196 patients with a 2:1 randomization ratio (SBRT: SRT). The study is powered at 80% with a two-sided alpha of 0.05 to detect a difference in 1-year OS of 40.3% vs. 22% (HR = 0.6), assuming a 15% drop-out/lost to follow-up rate. Conduct to Date: This trial was activated on October 31, 2024. Supported by CCS grant #707213; CIHR #175014. [1] Takahashi M, Takahashi M, Komine K, Yamada H, Kasahara Y, Chikamatsu S, et al. (2017) The G8 screening tool enhances prognostic value to ECOG performance status in elderly cancer patients: A retrospective, single institutional study. PLoS ONE 12(6): e0179694. https://doi.org/10.1371/journal.pone.0179694. Clinical trial information: NCT06641791. Research Sponsor: Canadian Cancer Society (CCS); 707213; Canadian Institutes of Health Research (CIHR); 175014.