TPS12141 **Poster Session**

A randomized phase III study comparing stereotactic body radiotherapy (SBRT) versus conventional palliative radiotherapy (CRT) for participants with painful non-spine bone metastases (NCT06391242).

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Background: Stereotactic body radiotherapy (SBRT) is efficacious in the treatment of painful spinal metastases [1]. Data are required regarding the efficacy feasibility, toxicity and clinical outcomes associated with SBRT in patients with painful non-spine bone metastases prior to widespread adoption of this technique. **Methods:** This is a Canadian Cancer Trials Group led multi-centre, phase III randomized controlled trial comparing SBRT to conventional palliative external beam radiotherapy (CRT) in patients with solid tumours and a dominant painful non-spine bone metastasis (worst pain score >2). *Treatment arms:* EBRT 20Gy/5fr (control) versus SBRT 35 Gy/5fr or 30Gy/5fr (experimental). *Primary objective*: To compare 3-month complete pain response (CPR) rate and analgesic intake assessed using the International Consensus on Palliative Radiotherapy Endpoints [2]. Secondary objectives evaluate pain response pattern at 1, 3 and 6 months and assess re-irradiation rates, fracture incidence within RT target site, incidence of Grade > 2 adverse events, image-based local control, and patient reported outcomes (EORTC QLQ-C30 and QLQ-BM22). *Statistical design:* The target accrual is 230 patients, randomized 1:1. The trial is powered at 80% with a two-sided alpha of 0.05 to detect an improvement in the CPR rate from 17% (CRT) to 34% (SBRT), accounting for a 15% missing data rate. *Conduct to Date*: Study was activated on June 26, 2024. Supported by CCS grant # 707213. [1] Sahgal, Arjun, et al. "Stereotactic body radiotherapy versus conventional external beam radiotherapy in patients with painful spinal metastases: an open-label, multicentre, randomised, controlled, phase 2/3 trial." *The Lancet Oncology* 22.7 (2021): 1023-1033. [2] Chow E, Hoskin P, Mitera G, Zeng L, Lutz S, Roos D, Hahn C, van der Linden Y, Hartsell W, Kumar E; International Bone Metastases Consensus Working Party. Update of the international consensus on palliative radiotherapy endpoints for future clinical trials in bone metastases. Int J Radiat Oncol Biol Phys. 2012 Apr 1;82(5):1730-7. doi: 10.1016/j.ijrobp.2011.02.008. Epub 2011 Apr 12. PMID: 21489705. Clinical trial information: NCT06391242. Research Sponsor: Canadian Cancer Society (CCS); 707213.