TPS5132 Poster Session

Androgen suppression combined with elective nodal irradiation and dose escalated prostate treatment: A non-inferiority, phase III randomized controlled trial of stereotactic body radiation therapy versus brachytherapy boost in patients with unfavourable risk localized prostate cancer (ASCENDE-SBRT; CCTG PR24; NCT06235697).

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Background: External beam radiotherapy (EBRT), brachytherapy boost and androgen deprivation therapy (ADT) is the evidence-based standard of care for unfavourable (unfavourable intermediate, high and very high) risk non-metastatic prostate cancer. Preliminary data demonstrate that treatment with 5 fractions of stereotactic body radiotherapy (SBRT) delivered to the pelvis and prostate with ADT is efficacious and tolerable in this patient population (Murthy Int J Rad Onc Biol Phys 2025) Other potential advantages associated with this treatment strategy include fewer treatment visits, lower cost, avoidance of a general anesthetic and decreased resource utilization. Rigorous evaluation of this treatment strategy within a clinical trial is required to inform adoption in practice. **Methods:** PR24 is a Canadian Cancer Trials Group led, intergroup, randomized phase III, non-inferiority study comparing pelvic EBRT + brachytherapy boost to SBRT (5 fractions delivering 40Gy to prostate and 25Gy to pelvis) in brachytherapy eligible, unfavourable risk, non-metastatic prostate cancer patients. All patients will receive risk-adapted duration of ADT. The primary objective is to determine if SBRT is non-inferior to conventional EBRT with brachytherapy boost in terms of disease progression free survival (PFS). Secondary objectives include a comparison between arms of: safety and tolerability; efficacy including PSA response rate at 4 years, metastasis-free survival, prostate cancer cause-specific survival, overall survival; patient-reported and economic outcomes. Biobanking for future correlative studies is included in study design. Statistical design: The target accrual is 710 patients over 3.6 years with 5-year follow-up up to rule out a target HR 1.65 (6.5% inferiority difference at 5-years) in PFS, using type 1 error rate 5% (one sided) and 80% power with 5% lost to follow-up. Conduct to Date: Study activation - March 2024. First patient enrolled - April 2024. Accrual to date: 45. Supported by CIHR grant #183644, NCTN grant #CA180863 and CCS grant #707213. Clinical trial information: NCT06235697. Research Sponsor: CIHR; 183644; NCTN; CA180863; CCS; 707213.