Canadian Cancer Society

Movember Translation Acceleration Grant

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PSMA PET/CT Guided Intensification of Therapy in Patients at Risk of Advanced Prostate Cancer (PATRON): A Pragmatic Phase III Randomized Controlled Trial

High-risk and recurrent prostate cancer is associated with poor rates of failure-free survival. We postulate that PSMA PET/CT, in providing a more accurate image of disease extent, will enable more effective targeting of radiotherapy and surgery. While studies exploring the diagnostic role of PSMA PET/CT have been extensively reported, trials seeking level 1 evidence of an associated improvement in cancer related outcomes are lacking.

Through the conduct of a Phase III randomized controlled trial, we plan to: 1) determine if PSMA PET/CT guided intensification of radiotherapy or surgery improves cancer outcomes compared to conventional imaging-guided therapy in patients at risk of advanced disease, 2) evaluate its impact on toxicity and quality of life, and 3) measure the cost-effectiveness of the PSMA PET/CT guided approach.

Patients with high-risk prostate cancer planned for curative-intent standard-of-care radiotherapy or surgery, or with biochemical failure after radical prostatectomy planned for salvage radiotherapy will be enrolled over 3 years (n=741). Those randomized to the investigational arm will have PSMA PET/CT prior to therapy. Based on the imaging results, treating physicians will intensify radiotherapy or surgery unless widely metastatic disease is found, in which case systemic therapy will be intensified.

Ultimately, for the value of PSMA PET/CT to be determined, the impact of this imaging on patient outcome must be evaluated. The Canadian landscape is uniquely poised to successfully undertake such a trial.