Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Prophylactic Versus Therapeutic Alpha-Blockers in Prostate Cancer Patients Undergoing Radical Course Radiation Therapy ± HDR Boost.
Protocole ID	PCS VII
ClinicalTrials.gov ID	NCT02220829
Type(s) de cancer	Prostate
Phase	Phase III
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	Montréal
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Statut	Fermé
But étude	Approximately 50%-95% of prostate cancer patients undergoing radiation therapy (RT) develop symptomatic urinary problems .These symptoms can significantly diminish a patient's quality of life during and shortly after therapy. Alpha1-blockers, such as Rapaflo, act to decrease resistance to urinary flow.This multi-institutional phase III trial is designed to compare standard of care versus preventive treatment with Rapaflo for prostate cancer patients, regardless of risk group, whose treatment consists of radical radiation therapy. We plan to recruit 188 patients across Quebec who will be randomized into two arms: rapaflo prescribed at start of radiation therapy or if/when symptoms appear.
Critères d'éligibilité	• Adult male 18 years of age or older • Patients with confirmed diagnosis of adenocarcinoma of the prostate. • The primary treatment should be external beam radiation therapy (EBRT) with or without high dose rate (HDR) brachytherapy boost. • Clinical or radiological diagnosis of T1a - T3b. • No limitation with respect to Gleason score. • No limitation with respect to total Prostate-specific Antigen (PSA) value. • Karnofsky performance score (KPS) of ≥ 70.
Critères d'exclusion	• Small cell cancer of the prostate • T4 disease, invading bladder or rectum. • Adjuvant or salvage radiation therapy • Brachy monotherapy • KPS < 70