Essai Clinique

Généré le 04 mai 2024 à partir de

Titre	Un essai randomisé de phase III sur la metformine chez des patients initiant une thérapie de déprivation d'androgène comme moyen de prévention et d'intervention au niveau du syndrome métabolique – L'étude PRIME.
Protocole ID	PRIME
ClinicalTrials.gov ID	NCT03031821
Type(s) de cancer	Prostate
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Support
Médicament	Metformine
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
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Statut	Fermé
But étude	The primary objective of this study will determine if there are differences between arms with respect to the proportion of patients who meet the diagnostic criteria for metabolic syndrome after 18 months of study treatmentIt is estimated that one in seven Canadian men will be diagnosed with prostate cancer in their lifetime. In 2015, approximately 23,600 Canadian men were estimated to be diagnosed with prostate cancer and 4,000 died of this diseaseAndrogen deprivation therapy (ADT) is a standard first-line treatment for men with incurable prostate cancer and has long been known to improve overall survival. It was recently shown that intermittent ADT (iADT) is non-inferior to continuous therapy, with modest improvement in quality-of-life measures being provided by the intermittent approach. Thus, iADT is considered a standard of care in patients with rising PSA after definitive local therapyAlthough the effectiveness of ADT is well established in patients with advanced prostate cancer, it is associated with important adverse effects as outlined below. The development of metabolic syndrome in particular is clinically important as it is associated with worsened quality of life and increased all-cause morbidity and mortalityAs ADT is now employed, alone or in combination with other therapies, in virtually all men with advanced prostate cancer for increasingly long periods of time (median survival of men presenting with newly diagnosed metastatic disease from recent clinical trials is at least 3 years, during which they are typically on continuous hormonal therapy), the burden of ADT toxicity among men with prostate cancer is significant and increasingThe investigators hypothesize that the addition of metformin to a program of intermittent ADT will reduce the proportion of patients with metabolic syndrome at 18 months after initiation of ADT and will reduce the severity of individual components of metabolic syndrome in men with advanced prostate cancer. To test this hypothesis, this is a randomized, double-blinded, placebo-controlled phase 3 clinical trial of metformin in patients undergoing iADT treatment.
Critères d'éligibilité	• Pathologically confirmed adenocarcinoma of the prostate. • Eligible for initiating intermittent androgen deprivation therapy with either: • Asymptomatic metastatic disease; or • Biochemical recurrence of prostate cancer: • PSA > 3 ng/mL after prior curative intent local therapy (i.e. prostatectomy); or • PSA ≥ 2 ng/mL above their nadir if previously treated with definitive radiotherapy. • Serum testosterone > 5 nmol/L. • Patient is able (i.e. sufficiently fluent) and willing to complete the quality of life questionnaires in

	either English or French. The baseline assessment must be completed within required timelines, prior to registration/randomization. Inability (lack of comprehension in English or French, or other equivalent reason such as cognitive issues or lack of competency) to complete the questionnaires will not make the patient ineligible for the study. However, ability but unwillingness to complete the questionnaires will make the patient ineligible. • Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements. Each patient must sign a consent form prior to enrolment in the trial to document their willingness to participate. • Patients must be accessible for treatment and follow-up. Investigators must assure themselves the patients randomized on this trial will be available for complete documentation of the treatment, adverse events, and follow-up. • Patients must be accessible for treatment and follow up. Patients registered on this trial must be treated and followed at the participating centre. Investigators must assure themselves the patients registered on this trial will be available for complete documentation of the treatment, adverse events, and follow-up. • Protocol treatment is to begin within 7 working days of patient randomization.
Critères d'exclusion	• Prior androgen deprivation therapy within 12 months of enrolment. • Prior androgen deprivation therapy associated with definitive treatment is permitted, if it has been completed at least 12 months prior to enrolment (i.e. last injection or tablet taken 12 months prior to enrolment). • Patients that meet ≥ 1 of the Canadian Diabetes Association criteria for the diagnosis of diabetes within 28 days of enrolment: • Fasting plasma glucose of ≥ 7 mmol/L; or • HbA1C ≥ 6.5%. • Patients currently taking metformin or who have taken metformin within 28 days or enrolment. • History of lactic acidosis or conditions that predispose to lactic acidosis: • Impaired Renal Function (eGFR < 45 mL/minute/1.73 m2); or • Liver disease, including alcoholic liver disease, as demonstrated by any of the following parameters: • AST >1.8 x the upper limit of normal • ALT > 1.8 x the upper limit of normal • Alkaline Phosphatase > 2x the upper limit of normal • Serum total bilirubin > 1.5 x the upper limit of normal (except for subjects with Gilbert's Disease who are eligible despite elevated serum bilirubin levels). • Alcohol abuse (habitual intake of ≥3 alcoholic beverages per day) sufficient to cause hepatic toxicity; or • Severe infection. • Congestive heart failure (defined as New York Heart Association Class III or IV functional status). • Patients with a history of other invasive malignancies, except adequately treated non-melanoma skin cancer or other solid tumours curatively treated with no evidence of disease for ≥ 5 years.