Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	Étude de phase 3, prospective, multicentrique, randomisée, en double aveugle, contrôlée contre placebo, à 2 groupes parallèles afin de comparer l'efficacité et la tolérance du traitement par masitinib en association avec docétaxel par rapport au traitement par placebo en association avec docétaxel chez les patients atteints d'un cancer de la prostate métastatique résistant à la castration (mCRPC) en première intention
Protocole ID	AB12003
ClinicalTrials.gov ID	NCT03761225
Type(s) de cancer	Prostate
Phase	Phase III
Stade	Métastatique
Type étude	Traitement
Médicament	masitinib
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	Sherbrooke
Investigateur principal	Dr Michel Pavic
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Statut	Fermé
But étude	The objective of this study is to evaluate the efficacy and safety of masitinib in combination with docetaxel and prednisone with respect to placebo in combination with docetaxel and prednisone in the treatment of first line metastatic Castrate Resistant Prostate Cancer (mCRPC). Approximately 580 patients will be randomized in 2 groups with a ratio 1:1. The primary outcome measure is progression free survival. Masitinib is a selective tyrosine kinase inhibitor that is thought to promote survival via modulation of immunostimulation-mediated anticancer effects and modulation of the tumor microenvironment.
Critères d'éligibilité	• Histologically or cytologically confirmed metastatic Castrate Resistant Prostate Cancer (medical or surgical castration: androgens deprivation by GnHR agonist or antagonist or patient with surgical castration; hormonal castration confirmed biologically (testosterone < 0.5ng/ml) with one of the following criteria: • Pre-treated with abiraterone with documented progressive disease, OR • Indicated for initiating docetaxel treatment (e.g., widespread visceral disease or rapidly progressive disease). • Patient with evidence of progressive metastatic disease as assessed according to the Prostate Cancer Clinical Trials Working Group 2 (PCWG2) recommendations. • Patient with adequate organ function as per protocol
Critères d'exclusion	• Patient who has been previously treated with chemotherapy.